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June 28, 2006

VIA FEDERAL EXPRESS

Mark B. McClellan, M.D., Ph.D., Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

RE:

CMS-1270-P -- Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other

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Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule to implement the Medicare durable medical equipment ("DME"), prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program ("Proposed Rule").

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from medical devices and nutritional products through laboratory diagnostics and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries.

The Proposed Rule is of particular interest to two Abbott divisions – Abbott Diabetes Care and the Ross Products Division. Abbott Diabetes Care manufactures diabetes care products, including self-monitoring blood glucose ("SMBG") systems, test strips, data management software, and accessories that help individuals with diabetes obtain the diagnostic information they need to control their disease. Through effective self-monitoring of blood glucose levels, individuals can take charge of their day-to-day diabetes care by adjusting medications, diet, and/or activity levels to achieve optimal diabetes self-management. The Ross Products Division is a dedicated leader in the research and development of specialized enteral nutritional products, which provide therapeutic nutritional support to patients who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources. Integrating the appropriate enteral nutritional intervention into care plans is essential to the health outcomes of patients with severe and chronic diseases like cancer, HIV/AIDS, chronic obstructive pulmonary disease ("COPD"), diabetes, and kidney disease. In most cases, enteral nutritionals are the prime source of the individual's nutrition, and the beneficiaries depend on the enteral products to live.

Abbott fully supports the Congressional goals of promoting high-quality care for Medicare beneficiaries while achieving improved management of costs, and we believe that the Proposed Rule must ensure that it balances both of these key Congressional objectives. We also agree with Congressional drafters of the competitive bidding statute that the program



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needs to be phased in judiciously, both geographically and through careful selection of products for inclusion in each phase of bidding. We are very concerned, however, that the proposed DMEPOS competitive bidding rule is overly broad and does not comply with Congressional directives to tailor competitive bidding in a way that protects the quality of care for Medicare beneficiaries. CMS's Proposed Rule could restrict beneficiary access to medically-necessary blood glucose monitoring and enteral nutrition products, resulting in adverse impacts on patient health care outcomes.

Our specific concerns and recommendations are highlighted in our Executive Summary and discussed in greater detail in our comments below. We appreciate the opportunity to offer constructive comments on how to structure competitive bidding in a way that will protect the availability of medically-necessary diabetes and enteral products, ensure beneficiary choice of home medical equipment suppliers, and promote high quality care for Medicare beneficiaries.

Executive Summary: Abbott's Comments on Proposed Competitive Bidding Rule

1. CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries and that have been successfully tested in a competitive bidding demonstration. Enteral nutrition and blood glucose monitoring systems represent two categories of products that CMS should exclude from competitive bidding.

As discussed in detail in our comments, blood glucose monitoring products should be excluded because:

- It would limit access to medically-necessary blood glucose monitoring equipment, which would compromise the beneficiary's ability to control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life.
- These products have never been tested in a competitive bidding demonstration, and the impact on patient outcomes has not been assessed; and
- It would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program.

Likewise, enteral nutrition products should be excluded from competitive bidding because:

 They are the beneficiary's sole source of nutrition, and necessary for the Medicare beneficiary to survive. If a patient does not have adequate access to specific enteral products, it could have an adverse clinical impact on the patient's overall health status and jeopardize patient safety.





- Enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested.¹
- The majority of Medicare enteral nutrition patients reside in skilled nursing facilities, which raises distinct clinical, quality, and operational issues that have not been successfully tested or resolved.
- 2. <u>If CMS considers including blood glucose monitoring or enteral nutrition products in any future phase of competitive bidding, we recommend that CMS:</u>
 - First do so on a limited basis in a single competitive bidding area ("CBA") in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved, as discussed below,
 - Include only products furnished in the home care setting (<u>i.e.</u>, not products furnished in the skilled nursing facility setting);
 - Establish appropriate subcategories to preserve access to blood glucose monitoring products with medically-necessary and distinct features, and require suppliers to include in their bids certain medically-necessary item features within the enteral product codes;
 - Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk associated with inappropriate substitutions of the disease-specific formulas in this category; and
 - Include enteral equipment in the grandfathering process, clarify that CMS intends to establish separate payment amounts for each enteral nutritional product and supply HCPCS code (rather than a bundled payment), and maintain current enteral pump rental payment policy.
- 3. We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.
- 4. We recommend that CMS adopt retail supplier proximity standards based on the Part D prescription drug program pharmacy access standards to preserve adequate patient access to medically-necessary blood glucose monitoring systems and enteral nutritionals, equipment, and supplies.
- 5. We support the voluntary, rather than mandatory, use of mail order suppliers.



Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report, prepared by the Center for Health Systems Research and Analysis and RTI International, November 2003, at 252.



- 6. We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.
- 7. We recommend that CMS exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians), mail order suppliers, and unaccredited suppliers when establishing pivotal bids and single payment amounts to promote fair and realistic pricing determinations and ultimately ensure beneficiary access to an adequate number of suppliers.
- 8. We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean).
- 9. We recommend that CMS not apply competitive bidding prices outside of competitive bidding areas until the results of the first phases of competitive bidding are fully assessed, the mandated reports have been submitted, and a separate rulemaking with public comment period is issued to adopt a suitable framework for the policy.
- 10. CMS should issue a separate rulemaking if it seeks to refine the current "gap fill" pricing methodology, and should not adopt "functional technology assessments" as currently proposed.





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Abbott's Detailed Comments on Proposed DMEPOS Competitive Bidding Rule

I. Comments Related to Blood Glucose Monitoring Products

A. <u>Legal and Policy Rationale for Exclusion of Blood Glucose Monitoring Products</u> [Criteria for Item Selection]

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve the Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because blood glucose monitoring products have not been tested at all, and because inclusion of these products could compromise quality of care for beneficiaries with diabetes, CMS should not include blood glucose monitoring products in the first phase of the competitive bidding program. If CMS considers including blood glucose monitoring products in any future phase of competitive bidding, we recommend that CMS first do so on a limited basis in a single competitive bidding area in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

The Medicare Modernization Act of 2003 ("MMA") authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. To the contrary, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that CBAs "may differ for different items and services," recognizing that all products will not be included in bidding. CMS acknowledges this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding."²

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk "3 While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on specific blood glucose monitoring products to sustain or support life.



^{2 71} Fed. Reg. 25,670.

³ Conference Report to Accompany MMA Report, 108-391 at page 575.



For instance, approximately half of individuals on dialysis have diabetes. They depend on blood glucose monitoring systems that avoid what the Food and Drug Administration ("FDA") characterizes as the "potential for life-threatening falsely elevated glucose readings" in the presence of certain dialysis solutions since it can be life-threatening if the falsely elevated glucose reading is treated with aggressive insulin therapy. As explained by an FDA advisory⁴:

We recently received a report of a patient who suffered irreversible brain damage following an aggressive insulin treatment that was given for elevated glucose readings. Unfortunately, the elevated glucose readings were incorrect because the glucose monitoring device, which was unable to distinguish between glucose and maltose, was reacting to the maltose in the intravenous immunoglobulin solution that the patient was receiving.

Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. There clearly are unique, patient-critical operational issues associated with blood glucose monitoring products, stemming from the complex therapeutic needs of the Medicare beneficiaries with diabetes and the need to protect access to certain medically-necessary product features, among others. Using Congress' own standards for exclusion, blood glucose monitoring products should be excluded from competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

CMS should exercise this statutory authority to exclude certain blood glucose monitoring products from the initial phase of competitive bidding that have greater therapeutic advantages for individuals. Such products include: those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that prevent falsely elevated glucose readings in dialysis patients receiving certain dialysis solutions, those that have multiple body site testing capabilities; and those that require small blood sample size and therefore minimize pain associated with testing. The therapeutic advantages of these products are discussed below.

CMS also has the statutory authority to exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." As we discuss below, inclusion of blood glucose monitoring products would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program, and thus they can and should be excluded from competitive bidding.



⁴ http://www.fda.gov/cdrh/oivd/news/glucosefalse.html.



If CMS decides to include any blood glucose monitoring products in Phase I, it should be done on a limited basis (i.e., one initial CBA) to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries with diabetes.

2. <u>Blood Glucose Monitoring Supplies and Equipment Were Not Tested in Competitive</u> Bidding Demonstrations

CMS should include in the first round of competitive bidding only those products that have been successfully tested in a prior competitive bidding demonstration project to ensure that CMS has adequate information regarding the impact of competitive bidding on patient access, medical outcomes, and beneficiary satisfaction. We note that CMS lists as a factor it will consider when determining whether a product is appropriate for competitive bidding the "Savings in the DMEPOS Demonstrations" associated with that product. We agree with CMS that this is an important factor for consideration in product selection.

CMS did not include blood glucose monitoring systems in the DMEPOS demonstration. We believe that CMS had strong policy and patient care reasons for not including blood glucose monitoring products in the demonstration; those reasons still apply. Equally important, CMS has no experience with the impact inclusion of such products would have on beneficiary care or overall health care spending. While the products that were included in the Polk County and San Antonio demonstrations generated a great deal of data, including information on beneficiary satisfaction, access to products, pricing, and supplier capacity issues, and this information has been subject to evaluation and careful review by CMS, its contractors, and the public, such data is completely lacking for blood glucose monitoring products.

CMS therefore should not include blood glucose monitoring products in the first phase of the competitive bidding program. Instead it would be more prudent for CMS to concentrate on those products that were successfully tested in the previous demonstrations. If CMS decides to include blood glucose monitoring systems in any future phase of competitive bidding, it should first test its impact on a limited scale (<u>i.e.</u>, in one CBA).

3. Complexity of Diabetes Patient Care Needs

According to the American Diabetes Association ("ADA"), diabetes is one of the nation's most debilitating, deadly, and costly diseases. There currently are 20.8 million Americans – or 7 percent of the population – with diabetes, and the pace of new cases is increasing. More than 10 million individuals age 60 years or older, or 20.9 percent of all people in this age group, have diabetes. Diabetes is the leading cause of kidney disease, adult-onset blindness, and lower limb amputations and a significant cause of heart disease and stroke. Diabetes contributed to 224,092 deaths in 2002. The mortality rate due to diabetes has increased by 45 percent since 1987 – at the same time the mortality rates due to heart disease, stroke, and cancer have actually declined. Effective management of diabetes – including monitoring and regulating blood glucose levels – is key to preventing numerous serious complications,



^{5 71} Fed. Reg. 25,671.

⁶ American Diabetes Association, available at www.diabetes.org.



including blindness, kidney and nerve damage, diabetic ketoacidosis, hyperosmolar (nonketotic) coma. and even death.⁷

Proper glucose monitoring requires careful selection of the meters and strips that are medically appropriate for the beneficiary's condition, taking into account the patient's comorbidities, interfering substances, and other health factors (such as visual impairments) that could affect the choice of a particular system. There currently are more than 30 blood glucose monitoring systems on the market. As discussed below, among these systems there are a wide range of capabilities and features, including advanced features designed to meet very specific patient health care needs. Blood glucose monitoring systems are not interchangeable, and clinicians need to determine and prescribe the features that best meet that patient's needs, considering comorbidities and other health factors.

For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. The FDA has warned that there have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy. 8 In fact, the FDA has posted many safety alerts on this issue, as recently as November 2005. The agency requires the package insert for these types of glucose monitoring systems to include a warning such as "Peritoneal dialysis solutions containing icodextrin cause overestimation of glucose test results" or "Patient receiving peritoneal dialysis using solutions containing icodextrin (e.g., Extraneal®, Icodial) should not use [this product]." Because approximately 50 percent of patients on dialysis have diabetes, it is critical that patients using these dialysis solutions in each CBA have access to blood glucose monitoring systems that minimize or eliminate interference with these solutions, such as monitoring systems that use GDH-NAD or glucose oxidase. Other blood glucose monitoring systems prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen, each of which can distort blood glucose readings for patients with such conditions as arthritis or gout. Beneficiaries in each CBA need to be able to access blood glucose monitoring systems that are unaffected by these common agents.

If CMS includes blood glucose monitoring systems in competitive bidding, it could limit access to blood glucose monitoring equipment with a greater therapeutic advantage to individuals, which would compromise the beneficiary's ability to monitor and control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life. We therefore recommend that CMS exercise its statutory authority to not include blood glucose monitoring systems in competitive bidding.



⁽ADA, 2005). See also the DCCT Trial and the United Kingdom Prospective Diabetes Study ("UKPDS").

⁸ See http://www.fda.gov/cber/safety/maltose110405.htm.



4. Interference with Coordinated Care/Chronic Care Demonstration

According to CMS itself, "Fragmentation of care is a serious problem, especially for Medicare beneficiaries," who on average see seven different physicians and have 20 prescriptions each year. The difficulties of coordination of care for individuals with diabetes, and its impact on health care outcomes, also have been documented in a recent series in the *New York Times*. For instance, one recent article pointed out that "a study last year by Georgetown University found that insurance restrictions on strips and other services for diabetics were reducing the quality of care." The same article also quoted an 82-year old individual with diabetes who observed that "Controlling my condition isn't that hard. . . The hard part are the things outside my control, like getting the test strips and the medicines." 10

The problems associated with fragmentation of care for diabetes patients and the need to carefully manage the diabetes and comorbidities of Medicare beneficiaries is the reason the federal government has included diabetes care in its major chronic care demonstration project. Specifically, the MMA authorized the development and testing of voluntary chronic care improvement programs, now called Medicare Health Support programs, to improve the quality of care and life for people living with multiple chronic illnesses. The programs are designed to help participants adhere to their physicians' plans of care and obtain the medical care they need to reduce their health risks, while providing savings to the Medicare program and beneficiaries. CMS selected beneficiaries with diabetes and/or congestive heart failure for inclusion in the Medicare Health Support program because they "have heavy self-care burdens and high risks of experiencing poor clinical and financial outcomes," and because of the prevalence of comorbidities. CMS notes that evidence indicates that "self-care support, education, and assistance in coordinating care for people with these conditions can be effective in improving clinical outcomes, reducing their healthcare costs, and improving participant and provider satisfaction."11 The Medicare Health Support programs are operated by organizations that were chosen by CMS through a competitive selection process. CMS has not discussed in the proposed rule how restricting beneficiary choice of suppliers or pharmacists through DMEPOS competitive bidding would impact coordination of care for Medicare beneficiaries with diabetes who are participating in Medicare Health Support programs. Moreover, CMS does not discuss how DMEPOS competitive bidding would affect the pay-for-performance approach established through the Medicare Health Support program. under which fees to organizations are based on meeting standards for quality improvement, savings to Medicare, and increased satisfaction levels in their assigned beneficiary populations - outcomes that could be affected by the restrictions imposed by competitive bidding. Likewise, CMS does not address how competitive bidding could undermine CMS's ability to evaluate the effectiveness of the Medicare Health Support programs for beneficiaries who live in DMEPOS CBAs.

More broadly, CMS should consider the adverse impact of competitive bidding on coordination of care for patients with diabetes, both for beneficiaries enrolled in the Medicare Health



⁹ See http://www.cms.hhs.gov/CCIP/02_Highlights.asp.

Urbina, Ian; "In the Treatment of Diabetes, Success Often Does Not Pay," New York Times, January 11, 2006.

See http://www.cms.hhs.gov/CCIP/downloads/MHSOverview012306.pdf.



Support program and for beneficiaries who coordinate their care through their clinicians, pharmacists, and other caregivers. For instance, Medicare beneficiaries who are enrolled in Medicare Part D may receive their oral medications, insulin, and syringes – along with pharmacist counseling -- through their pharmacy. Including blood glucose monitoring products in competitive bidding could further fragment care for this population.

5. Limited Potential for Cost Savings

According to the ADA, one out of every 10 health care dollars is spent on diabetes and its complications. Direct and indirect spending on diabetes care reached \$132 billion in 2002, \$40.3 billion of which was spent for inpatient hospital care and \$13.8 billion for nursing home care for people with diabetes. Cardiovascular disease accounted for more than \$17.6 billion of the direct medical costs for diabetes in 2002. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes. 12

Competitive bidding risks jeopardizing beneficiary access to the most appropriate blood glucose meters and strips, which could make it more difficult for beneficiaries to control their diabetes, leading to increased complications and costly hospital care. ¹³ In fact, in a June 2006 report to Congress, the Medicare Payment Advisory Commission ("MedPAC") points out that "longer term savings could come from improved management of conditions such as diabetes because poor glucose control in diabetics can lead to worse cardiovascular health in the longer term." ¹⁴ CMS clearly has the statutory authority to exclude from competitive bidding those products "for which the application of competitive acquisition is not likely to result in significant savings." Given the potential for increased Medicare costs – particularly Part A hospital costs – resulting from complications associated with inappropriate diabetes care, CMS should undertake an assessment of the potential financial impact on the Medicare program related to diabetes complications prior to including such products in competitive bidding.

B. <u>Significant Clinical and Technological Distinctions of Blood Glucose Monitoring Products – Risk of Limiting Access to Medically-Necessary Features [Physician Authorization/ Treating Practitioner; Conditions for Awarding Contracts]</u>

<u>Abbott Recommendation</u>: CMS should preserve access to products with medically-necessary features. <u>If</u> CMS includes blood glucose monitoring products in <u>any</u> future phase of competitive bidding, CMS should exercise its statutory authority to establish separate subcategories within codes for bidding purposes to recognize blood glucose



See, <u>e.g.</u>, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).

Agency for Healthcare Research and Quality, Economic and Health Costs of Diabetes (2005).

¹⁴ MedPAC "Report to the Congress: Increasing the Value of Medicare" (June 2006).



monitors and strips with advanced features (<u>e.g.</u>, those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that are safe for use by beneficiaries undergoing dialysis; those that have multiple body site testing capabilities, and those that require small blood sample size and therefore minimize pain associated with testing, increasing compliance and improving health outcomes). CMS should either exclude the advanced subcategories from bidding or require suppliers to bid on all subcategories. Moreover, bidding suppliers should only supply blood glucose monitoring systems that offer beneficiaries 24/7 manufacturer support.

There is only one HCPCS code for all blood glucose test strips (A4253 Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and one blood glucose meter HCPCS code (E0607 -- Home blood glucose monitor) that encompasses almost all of the meters currently on the market. These codes have been in place for over 15 years. During this time, meter and strip technologies have changed significantly, and now there are important features that improve accuracy and promote testing compliance. Particular features of products within these codes provide a greater therapeutic advantage to individuals, including preventing potentially life-threatening false readings in the presence of interfering substances.

The MMA provides CMS with the authority to establish separate subcategories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. Specifically, the statute provides the following:

CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

In a number of situations, there are blood glucose monitoring systems that provide a clear therapeutic advantage to individuals, such as by preventing false glucose level readings that could lead to ineffective or potentially harmful medical interventions. For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. There have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy. In addition, beneficiaries using acetaminophen for arthritis or gout must use blood glucose monitoring systems with low or negligible interference from acetaminophen or they could receive inaccurate glucose level information and subsequently make inappropriate or harmful treatment decisions. Also, it is now well established that patients with diabetes have elevated uric acid levels; many systems using glucose oxidase are severely affected by elevated uric acid levels. Likewise, ascorbic acid (vitamin C) in elevated doses is widely used by many consumers, yet it can interfere with some glucose monitoring systems. Other systems provide therapeutic advantages because they have multiple body site testing capabilities or require smaller blood sample size, thereby minimizing pain associated with testing and enhancing beneficiary compliance with testing regimens.

Beneficiaries and their clinicians must have access to the most clinically-appropriate blood glucose monitoring system for their conditions. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer advanced equipment and supplies — unless compelled to do so — because of concerns that their bids will





not be low enough to be selected, which would jeopardize their opportunity to serve beneficiaries in the bidding area. Beneficiary access to these therapeutically and clinically necessary features could then be compromised.

Therefore, if blood glucose monitoring products are included in any future stage of competitive bidding, CMS should exercise its authority to protect patients by establishing subcategories within the blood glucose meter and test strip HCPCS codes to recognize these advanced features, and either: (1) exclude the advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Our recommendations for subcategories are presented below. We recommend that CMS establish a public review and comment period regarding any subcategories it develops.

Moreover, in recognition of the unique and critically-important role of manufacturer education and technical support for patients using blood glucose monitoring systems, we recommend that CMS require that suppliers may only submit bids for any category or subcategory of blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week manufacturer support. Unlike many other segments of the DMEPOS industry, education of and technical support for patient using blood glucose monitoring systems ideally is performed by the manufacturer, rather than by the DMEPOS supplier. As noted, there currently are more than 30 blood glucose monitoring systems available to suppliers and beneficiaries. A single supplier simply cannot know the technical intricacies of every monitoring system. Such manufacturer-specific knowledge is critical, since a misunderstanding or misinterpretation of results could lead to erroneous treatment decisions resulting in adverse health outcomes (such as the potentially deadly administration of too much insulin). A single manufacturer can receive between 75,000 and 100,000 calls from patients, caregivers, and health care providers in a single month. Manufacturers of high-quality blood glucose monitoring systems like Abbott have intensely-trained professionals that provide technical support and professional guidance on how to operate the equipment, including responding to questions and concerns in multiple languages. These staff members are trained to distinguish between user and technical errors. and to assist beneficiaries with their questions and concerns regarding effective management of their diabetes, and often encourage patient follow-up with their health care providers. Not every manufacturer offers these critical services, however. There is a danger that under the competitive bidding framework, there will be an incentive for suppliers to bid on the least expensive products within a code, even if the manufacturers of these products do not provide comprehensive patient support for their products. This would not promote quality of care for Medicare beneficiaries, a key goal of lawmakers in the MMA. Therefore, if CMS includes blood glucose monitoring products in any future phase of competitive bidding, it should specify in its request for bids that that suppliers may only submit bids for blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week manufacturer support. CMS or its contractors should provide suppliers with a list of eligible equipment under this requirement.

Recommendations for Subcategories

We recommend that CMS establish the following subcategories within codes A4253 (Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and E0607 (Home Blood Glucose monitor) if these products are included in any future phase of competitive bidding:





HCPCS	Descriptor	Subcategory	Descriptor
A4253	Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips	A	Protection Against Interfering Substances
		В	Safe with Commonly-Used Dialysis Solutions
		С	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		Е	Aids for Visual Impairments
		F	Testing Alarms
E0607	Home Blood Glucose Monitor	Α	Protection Against Interfering Substances
		В	Safe with Commonly-Used Dialysis Solutions
		С	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms

CMS should either: (1) exclude these advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Additional information regarding the clinical efficiency, value, and therapeutic advantages of these products follows.

1. Protection Against Interfering Substances

Blood glucose monitoring systems vary in their ability to minimize interference from certain common substances, such as aspirin, acetaminophen used for arthritis or gout treatment, elevated uric acid levels, or ascorbic acid (vitamin C) in elevated doses. Interference effects may result from relatively high voltages applied to the blood glucose test strips, interference from oxygen, or enzyme interactions. For instance, some strips, including the FreeStyleTM Blood Glucose Monitoring Strip, use glucose dehydrogenase -- rather than on glucose oxidase -- as an enzymatic catalyst during its reaction with glucose. Unlike glucose oxidase, oxygen is not involved in the reaction pathway of glucose dehydrogenase, and therefore interference by oxygen -- a problem with older technology devices -- is substantially reduced.

If test results are distorted by the inability of a blood glucose monitoring system to minimize interference from these common substances, it could lead to inappropriate treatment decisions that could have an adverse impact on beneficiary health. CMS therefore should establish a subcategory of meters and test strips that minimize interference and either exclude this subcategory from competitive bidding, or require suppliers to bid separately on the subcategory.





2. Safe with Commonly-Used Dialysis Solutions

Blood glucose monitoring and safety of patients undergoing dialysis is particularly important because approximately fifty percent of all dialysis patients have diabetes. The FDA has warned, however, that certain blood glucose monitoring systems provide falsely elevated glucose readings in patients receiving certain dialysis solutions. These falsely-elevated glucose readings can be life-threatening if they result in inappropriately aggressive insulin therapy. Serious injuries and deaths from such false glucose readings have occurred.

In November 2005, the FDA issued an alert entitled "Important Safety Information on Interference With Blood Glucose Measurement Following Use of Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products. ¹⁵ In light of the "potential for life-threatening falsely elevated glucose readings," the FDA warns that patients who receiving products containing the sugars maltose or sugars which are metabolized to maltose should "[u]se only test methods not affected by the presence of maltose, galactose, or d-xylose, such as glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase- or glucose hexokinase-based test methods."

Beneficiaries undergoing dialysis in every CBA must have available blood glucose monitoring systems that have been determined by the FDA to be safe for use by peritoneal dialysis patients. CMS should either exclude from competitive bidding blood glucose monitoring systems that are safe for use with commonly-used dialysis solutions, or establish a subcategory for these meters and strips and require suppliers to bid separately to supply meters and strips that are safe for this population.

3. Small Blood Sample Size - 1.0 Microliter or Less

Certain strips require a smaller sample size (for example the FreeStyle system requires approximately 0.3 microliter of blood, compared to as much as 4 to 5 microliters in older meters). The smaller volume is obtained by a less invasive blood draw mechanism that lowers pain, which is a major barrier to regular blood testing for people with diabetes. This improved technology encourages regular testing and good glucose monitoring and control. In addition, a smaller blood sample requirement can reduce the need for retests due to the meter registering "insufficient blood." The FDA reports 16 that users whose meters require less blood would have this insufficient blood retest problem less often – avoiding strip wastage. Likewise, some monitoring systems can measure the adequacy of the collected blood sample size, which ensures that the test starts only when enough blood has been collected, which again minimizes errors and retests and decreases costs associated with wasted strips. Beneficiaries in every CBA need access to blood glucose monitoring systems with this feature.



See http://www.fda.gov/cber/safety/maltose110405.htm.

FDA, "Glucose Meters & Diabetes Management" (http://www.fda.gov/diabetes/glucose.html).



4. Blood Samples Accessed from Multiple/Alternative Body Sites

Some blood glucose monitoring systems, including the FreeStyle system, can effectively access samples from multiple body sites with fewer nerve endings per square inch than the fingertips. Therefore testing can be done using less painful sites like forearms, upper arms, thighs and calves. The greater flexibility in sites from which blood can be drawn, with lower pain thresholds, promotes patient compliance with testing. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.¹⁷

5. Aids for Visual Impairments

Some blood glucose monitors provide verbal instructions and results for safe and effective testing by individuals with vision impairment. Many users perform glucose tests in dim light condition. A monitor (such as the FreeStyle Flash) that has a backlit display and a test light illuminating the test strip area can help reduce test errors and decrease costs associated with wasted strips.

6. Testing Alarms

Adherence to blood glucose monitoring is a challenge for some patients. Certain monitors (such as the FreeStyle Flash and FreeStyle Freedom) allow the user to program up to four daily alarms to remind them to test. As previously noted, frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

Abbott Recommendation: CMS should ensure that beneficiaries have adequate access to retail suppliers. Mail order suppliers should not skew CMS's capacity calculations in a competitive bidding area. CMS should not overestimate the ability of blood glucose monitoring system suppliers to expand capacity. CMS should exclude bids from mail order suppliers in determining the pivotal bid and single payment amounts since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers.

CMS should preserve beneficiary access to retail suppliers and pharmacies. Indeed, blood glucose monitoring products are available at over 50,000 pharmacies nationwide. Beneficiaries rely on their pharmacies to assist in the management of their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes. Competitive bidding should not disrupt this important network for beneficiaries



¹⁷ See, <u>e.g.</u>, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).



CMS is proposing that beneficiaries have a choice of at least two suppliers in a bidding area. We are concerned that two suppliers for a large CBA could be insufficient to provide beneficiaries with adequate access to a retail pharmacy. Instead, we propose that CMS apply its Part D retail pharmacy access standards to the DMEPOS competitive bidding program. These standards have been an important protection for beneficiaries enrolled in Part D, and offer a tested framework for the competitive bidding program to adopt. Specifically, under the Part D program, drug plans must establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

While a Part D plan's pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order, these pharmacies do not count towards fulfilling the plan's pharmacy access requirements. We recommend adopting such a model under DMEPOS competitive bidding. Thus, If CMS decides to allow mail order suppliers to bid in DMEPOS competitive bidding, those mail order suppliers should <u>not</u> count towards the two-supplier minimum that CMS is establishing in each CBA.

CMS also should give greater weight to retail suppliers when determining supplier capacity to ensure that the presence of mail order suppliers does not reduce the number of retail suppliers available to a beneficiary. This is particularly important since the draft DMEPOS quality standards state that mail order services may <u>not</u> be used "for the initial delivery, set-up, and beneficiary education/training for certain DME equipment and supplies," and CMS must ensure that beneficiaries have adequate access to retail suppliers who can supply these critical services.

In the preamble to the Proposed Rule, CMS asserts that "most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor." We believe CMS is misinformed regarding the labor required to furnish appropriate blood glucose monitoring supplies, and we are concerned that this could lead CMS to approve fewer diabetes suppliers in a bidding area than is truly necessary to adequately meet beneficiary demand. Under the draft DMEPOS supplier standards, diabetes suppliers must provide extensive beneficiary services, including meeting detailed standards regarding product delivery, set-up, training, equipment usage and cleaning, and troubleshooting. The supplier also is responsible for follow-up services, including continuing communication with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary; periodically reviewing the service plan with the treating physician or clinicians regarding the beneficiary's medical condition and the continued use and tolerance of the equipment and supplies; and communicating any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary's use of equipment and supplies to the treating physician within 24 hours of determination. CMS





should recognize these important diabetes supplier responsibilities and ensure that there is sufficient supplier capacity to meet beneficiary needs.

CMS does not discuss how, if it contracts with mail order suppliers, it would consider mail order bids in determining the pivotal bid and single payment amounts. We believe it is obvious that CMS could not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. In fact, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because mail order suppliers would not be providing the same level of beneficiary service, their bids would reflect lower costs than those of retail suppliers. Any comparison of the two types of bids (retail and mail order) would be particularly unfair to small retail suppliers, and could lead to inappropriate payment policies and capacity determinations. CMS should develop standards for the separate consideration of mail order bids before including mail order suppliers in competitive bidding.

We also want to point out that CMS should consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly individuals with diabetes.

D. <u>Competitive Bidding Areas/Nationwide or Regional Mail Order Competitive</u> Bidding

<u>Abbott Recommendation</u>: We support the voluntary, rather than mandatory, use of mail order suppliers.

Many beneficiaries with diabetes obtain their medical supplies and insulin through one of the 50,000 pharmacies that supply blood glucose monitoring products. Access to pharmacies is important for beneficiaries in managing their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes. Mandating the use of mail order suppliers for blood glucose monitoring supplies would prevent beneficiaries with diabetes from using one source to coordinate the pharmaceuticals, medical supplies, and equipment necessary to manage their complex medical conditions. Moreover, pharmacies and other retail suppliers can play an important role in continuing beneficiary education, training, and troubleshooting regarding their blood glucose monitoring equipment, a role that would be jeopardized by mandating mail-order replacement of supplies. Mail order suppliers would not be able to provide timely care if a beneficiary needs emergency refills. We therefore do not believe that "furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by national mail order suppliers," as CMS stated in the preamble, and we urge CMS to reject this proposal.

If CMS decides to allow mail order suppliers to participate in competitive bidding, we recommend that it be voluntary for beneficiaries – just as CMS has provided under the Part D prescription drug benefit. Moreover, CMS should ensure that all appropriate DMEPOS quality





standards are met, including that the mail order suppliers furnish products and supplies that are consistent with the clinician's order, meet the product specifications as prescribed by the clinician, and that qualified staff are available to respond to beneficiary concerns and needs.





II. Comments Related to Enteral Nutrition Equipment and Supplies

A. <u>Legal and Policy Rationale for Exclusion of Enteral Products [Criteria for Item Selection]</u>

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested, and because inclusion of these products could compromise quality of care for beneficiaries who rely on enteral nutrition, CMS should not include enteral nutrition products in the first phase of the competitive bidding program.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

As previously noted, the MMA authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. Instead, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that competitive bidding areas "may differ for different items and services," recognizing that all products will not be included in bidding. CMS notes this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." 18

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk "19 While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on enteral products to sustain or support life because they are the beneficiary's sole source of nutrition. If a patient does not have access to specific enteral products, it could compromise the patient's health, accelerate the disease process, and in serious cases lead to medical complications that could endanger the patient's life (i.e., aspiration resulting from incorrect feeding, inappropriate nutritional provided for a particular disease state). Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. Using Congress' own standards for exclusion, enteral products should be excluded from competitive bidding.



^{18 71} Fed. Reg. 25,670.

Conference Report to Accompany MMA Report, 108-391 at page 575.



Moreover, there apparently was confusion among the Congressional authors of the MMA's competitive bidding provision regarding the status of enteral products under competitive bidding. As CMS is aware, unlike most products in DMEPOS categories (e.g., orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ. ²⁰ A House Ways and Means Committee press release issued at the time of MMA passage states that the competitive bidding statute: "Exempts all prosthetics and implantable (Class III) devices" (emphasis added). ²¹ Lawmakers were mindful of the special safeguards needed to protect beneficiaries that rely on prosthetic devices that sustain and support life, and they concluded that the competitive bidding framework was inappropriate for these critical products. Thus, it is appropriate and consistent with Congressional intent for CMS not to include enteral products in competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

As discussed below, certain enteral nutritionals have a greater therapeutic advantage to individuals with certain medical conditions. For instance, some specialized medical nutritional products are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS, kidney disease, pulmonary disease, Crohn's disease, and diabetes, and it would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional. Other enteral nutritionals are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. CMS should recognize the unique clinical nature of these products and their important role in comprehensive chronic disease care plans by excluding them from competitive bidding.

The MMA also provides statutory authority to phase in competitive bidding based on "items and services that the Secretary determines have the largest savings potential," and to



Medicare National Coverage Determinations Manual (CMS Pub. 100-03), §180.2 - Enteral and Parenteral Nutritional Therapy, "Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof."

Ways and Means Committee, "Medicare Prescription Drug, Improvement, and Modernization Act of 2003 -- Medicare DME Freeze And Competitive Bidding Saves Beneficiaries and Taxpayers Money," available at http://waysandmeans.house.gov/media/pdf/healthdocs/dmesummary.pdf.



completely exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." Inclusion of enteral products would not achieve cost savings, since complications associated with inappropriate enteral care could result in higher overall health care costs for the Medicare program.

Research consistently shows that malnutrition – a state of inadequate or unbalanced nutrition - is a hidden cause of poor health outcomes and rising health care costs in the United States. There are also many studies that confirm the benefits of nutrition intervention including decreased morbidity and mortality, improved quality of life, and decreased length of stays and care costs. American Dietetic Association studies show that for every \$1.00 spent on nutrition intervention, at least \$3.25 is saved. Continuous monitoring and assessment of a patient's nutrition status is essential in the prevention of major complications like anemia, bone fusion failure, wound and joint infection, pressure ulcers, septicemia, pulmonary embolus, pneumonia, and others that add significant health care costs to the system. Competitive bidding risks jeopardizing beneficiary access to the most appropriate enteral nutrition products and services, which could interrupt care plans resulting in increased hospital admissions and increased home nursing services (covered under Medicare Part A). In addition, the prevalence of Medicare enteral use among nursing home patients and the strong case for excluding nursing homes from competitive bidding (detailed below) diminishes the potential for cost savings by including enteral products from competitive bidding, as the final DMEPOS demonstration project evaluation report concluded.

2. Complexity of Patient Care Needs

The proposed competitive bidding structure – which could result in dramatically fewer suppliers, diminished patient choice of suppliers, and decreased access to a range of medically-necessary items and services -- could have a particularly significant and negative impact on clinically-intensive patients who rely on enteral nutrition.

Unlike most products in DMEPOS categories (<u>e.g.</u>, orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ. Enteral nutrition is necessary for the Medicare beneficiary to survive. Thus, enteral products have both a distinct statutory Medicare benefit category and a unique clinical role as a beneficiary's sole source of nutrition.

Enteral nutrition is the delivery of necessary calories, nutrients, and other therapeutic ingredients through a tube placed into the gastrointestinal ("GI") tract (either directly into the stomach or through the small intestine), bypassing the mouth. Enteral nutrition is used by patients who have a disease or non-function of the structures that normally permit food to reach the small bowel, or a disease which impairs digestion and absorption of an oral diet. It is essential for patients who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources and for patients who are at risk of malnutrition. These patients include those patients with cancer, HIV/AIDS, stroke, multiple sclerosis, cerebral palsy, Parkinson's Disease, Amyotrophic Lateral Sclerosis, diabetes mellitus, liver failure, chronic renal failure, inflammatory bowel disease, among many others. Tube feeding is vital to sustain these patient's lives and to address their special medical needs. This is most often the individual's only form of nutrition, and choosing the specific enteral nutrition intervention strategy and integrating it with medical, surgical, and pharmacologic care is crucial to the overall health status of a beneficiary.





As recognized in the draft DMEPOS quality standards, beneficiaries using enteral products are subject to a wide range of complications from tube feeding, including constipation and nausea/vomiting, persistent or progressive abdominal pain, cramping, bloating, fullness or burning with feedings, infections, and leakage around the tube. Moreover, patients using enteral feeding often have comorbidities that complicate patient care, such as pressure sores, pneumonia, anemia, and infections. Serious metabolic complications like hypertonic or isotonic dehydration or overhydration can occur if the fluid and electrolyte status of a tube-fed patient is not monitored closely and correctly. Mechanical problems also are often associated with some aspect of the feeding tube itself: tube size, material, or location of the Gl tract. For example, aspiration pneumonia, a potentially lethal mechanical complication, may occur from compromise of the lower esophageal sphincter by a large-caliber feeding tube or from dislodgment or misplacement of the feeding tube. Thus, the complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies.

When a beneficiary is placed on enteral nutrition, the clinician must determine the most appropriate site and access route for feeding based on patient-specific factors such as the physiology of the GI tract, risk of pulmonary aspiration of gastric contents (entry of gastric contents into the lungs during breathing), comorbidities, and the length of time enteral support will likely be needed. The clinician then must assess which products, including formula and in some cases nutrients, pumps, and tubes, are most effective for the individual patient's situation. Each patient has individualized nutrition needs, and there are several formula characteristics the clinician needs to consider, including complexity of nutrients (some formulas contain nutrients in their complex forms, while others have nutrients that are in a simpler form (predigested) for patients who have absorption problems), osmolality, caloric density (calorically dense formulas can be used for patients with fluid restrictions, fluid intolerance, or high energy requirements), micronutrient content (electrolytes, vitamins, minerals and trace elements), fiber, lactose, viscosity, and water content.

As discussed in greater detail below, there is a range of enteral products available within the same HCPCS code, but many of those products are designed for distinct patient needs and are not interchangeable. If a patient does not have access to specific enteral products, it could compromise the patient's health, and in serious cases could lead to a progressive decline in their condition and ultimately endanger the patient's life. Yet under the Proposed Rule, a supplier would only need to furnish one product within a HCPCS code. As a result, products designed for specific diseases could simply be unavailable through contract suppliers in a particular area, creating a gap in the availability of life-sustaining products. Before competitive bidding could be applied to enteral products, CMS would need to establish a mechanism to ensure that each product necessary for a patient's disease state, physiology, or other medical condition is available to the beneficiary in every locality.

A distribution system based on a competitive bidding methodology and low bid incentives also does not adequately recognize the intense supplier services required by the fragile patient population using enteral equipment. Compared to the provision of other DMEPOS products, enteral suppliers are responsible for detailed caregiver and beneficiary education, including steps to resolve common feeding problems, assembly, use, storage and maintenance of all equipment and supplies, cleaning the gastrostomy/jejunostomy site, setting up and cleaning equipment, and recognition and appropriate response to various types of complications, proper tube positioning; formula storage and safety; and problems associated with tube feedings. Because enteral formulas are rich media for promoting microbial growth, all enteral





feeding systems require meticulous care. Enteral nutrition patients often require other DMEPOS items and services associated with the patient's underlying medical condition and comorbidities; restricting access to suppliers based on the lowest cost would fragment patient care and could have a negative impact on medical outcomes.

Given that these products sustain and support life and have an extensive service component, we are concerned that competitive bidding could result in inadequate pricing for products. This would present an unreasonable risk that patients would not have access to needed enteral products and quality care. CMS therefore should use its statutory authority to exclude enteral products from competitive bidding.

If CMS nevertheless does not exclude all enteral products from competitive bidding, CMS should: (1) limit inclusion initially to a single CBA to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries using enteral nutrition products; (2) limit competitive bidding to enteral products in the home care setting (rather than in a SNF); (3) exclude specialized nutrients designed for disease-specific and patient-specific needs from competitive bidding; (4) ensure that product are included within certain HCPCS codes to reflect the clinical efficiency and value of certain features; and (5) and address certain other operational issues, as discussed below.

3. Enteral Products were Shown to be "Not Well Suited" for Competitive Bidding in Prior Demonstration

When Congress enacted the MMA, it appears lawmakers believed that the competitive bidding demonstrations were a complete success. For instance, according to the House Ways and Means Committee, "Competitive Bidding Demonstration Was Successful," and under the first round of contracts, "Access to quality equipment was maintained" and "beneficiary satisfaction remained high." Likewise, CMS states in the preamble to the proposed rule that "The competitive bidding demonstrations . . . were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program and offered beneficiaries sufficient access and a quality product."

However, these assessments fail to distinguish the results for enteral nutritional products from the other tested products. CMS included enteral nutrition products in phase one of the Polk County demonstration. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. Indeed, because of the high volume of use of enteral products in the nursing home setting, rather than the home setting where other DMEPOS items are predominantly delivered, CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings.

CMS states that one of the factors it will consider when determining whether a product is appropriate for competitive bidding is whether it has been successfully tested in a competitive bidding demonstration. In light of the negative evaluation enterals products received in the





Polk County demonstration, CMS should not include enteral products in competitive bidding unless the agency successfully tests it in a limited area (<u>i.e.</u>, one CBA) and sufficient operational safeguards are in place to promote beneficiary satisfaction and ensure quality of care.

B. <u>Limitation on Scope of Enteral Products [Criteria for Item Selection, Submission of Bids under the Competitive Bidding Program, & Physician</u>
Authorization/Treating Practitioner]

<u>Abbott Recommendation</u>: <u>If</u> CMS considers including enteral nutrition products in any phase of competitive bidding, we recommend that CMS:

- (1) Do so only on a limited basis in a single competitive bidding area in order to monitor the impact and potential adverse impacts on beneficiary health, and only after adequate quality standards and other operational safeguards are in place;
- (2) Add as a criteria for item selection those products used primarily in the home care setting (<u>i.e.</u>, not in a skilled nursing facility setting), just as CMS adopted in two of the three rounds of the competitive bidding demonstration project;
- (3) Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk from inappropriate substitutions of formulas in this category; and
- (4) Exercise its statutory authority to require suppliers to guarantee access to enteral products with specific medically-necessary features.
- 1. Single Competitive Bidding Area

If CMS includes enteral products in any phase of competitive bidding, there are unique, patient-critical operational issues that must be addressed, stemming from the complex therapeutic needs of the Medicare beneficiaries who rely on these products, the significant use of enteral product in the skilled nursing facility setting; the need to preserve access to specialized nutritional formulas; the patient-specific nature of selecting the appropriate specialized enteral nutrients, and the need to protect beneficiary access to certain enteral equipment and supplies with medically-necessary product features. Because enteral nutrition was not successfully tested in a previous demonstration, CMS needs to ensure that it develops a framework that adequately addresses the problems encountered in the demonstration and preserves access to specialized formulas and equipment. Thus if CMS decides to include enteral products in any phase of competitive bidding, it should do so first in a single competitive bidding area to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care and safety of beneficiaries using enteral nutrition products.





2. <u>Limit Competitive Bidding to Home Care Setting: Unique SNF Site-of-Care</u> and Patient Severity of Illness Issues

As we discuss in greater detail below, unlike most other items of DME that may be subject to competitive bidding, enteral nutrition can be covered under Part B in the SNF setting in addition to the home care setting. Indeed, approximately 60 percent of Medicare enteral nutrition patients reside in SNFs.

CMS is proposing to require SNFs to participate in competitive bidding or contract with a winning supplier in order to furnish DMEPOS to their residents. However, competitive bidding has not been successfully tested in the nursing home setting, and the pilot failed to show significant savings. Moreover, the clinical needs of patients using enteral products in SNFs, the CMS quality standards, and the mechanism of distribution of products in the SNF are quite distinct from the home care setting. We therefore recommend that CMS not include SNFs initially in competitive bidding, and the agency should carefully consider the following issues before expanding competitive bidding to include SNFs.

a. Level of Care in a SNF Different than for Home Care Patients

Medicare patients in the SNF setting are often medically-complex with multiple comorbidities, particularly compared to beneficiaries in the home setting. Their need to be in a SNF is based on multiple clinical conditions and diagnoses, physical limitations, and need for assistance with activities of daily living. Beneficiaries receiving enteral nutrition rely heavily on the healthcare services that accompany the delivery of the enteral nutrition. In fact, the need for enteral nutrition is a qualifier for the "Clinically Complex" category under Medicare Part A prospective payment system rates. The services needed by SNF patients are considerably different than patients in the home care setting, and their treatment plans must be carefully managed and coordinated by their SNF. That is why the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") publishes separate Standards for Tube Feeding for different sites of care, including the home care setting and the SNF setting. Including enteral products for patients in the SNF setting could seriously interfere with established and functioning care plans, which could result in medical complications that increase overall costs of care to the Medicare program

b. CMS Has Not Successfully Tested Including Products Furnished to Institutional Patients in Competitive Acquisition

Although CMS included enteral products in the first round of the Polk County competitive bidding demonstration, beneficiaries living in SNFs could receive these products from nondemonstration suppliers that accepted the demonstration fee schedule. CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. We are concerned that in the





Proposed Rule, CMS characterizes the demonstrations as successful without noting that the negative evaluation of the inclusion of enteral products.

Under the Proposed Rule, CMS is proposing a different framework for including SNFs in competitive bidding than was tested in Polk County. SNFs would be mandated to use a winning supplier. This specific mechanism has not been tested before, so CMS has no data on its impact on beneficiary care. Before CMS considers extending competitive bidding to enteral products furnished in the institutional setting, the concept should be successfully tested in a more limited environment.

c. Competitive Bidding Could Jeopardize SNF Control over Beneficiary Care

Due to the level of services SNFs provide, they operate with higher fixed costs than home medical equipment companies, which could compromise their ability to submit competitive bids to maintain care of their residents. If a SNF is not a winning bidder, it could force the SNF to contract with a third-party for services they handle themselves today, creating inefficiencies in nursing home care. In addition, SNFs would be restricted in contracting with the most appropriate suppliers to help manage the patient's total care needs, including DMEPOS, drugs, and medical and ancillary services – even though the SNF is ultimately responsible for the quality of care furnished to the resident. Including SNFs in competitive bidding also could complicate continuity of medical care for patients, especially if a patient must change suppliers when they move from Part A to Part B coverage. It also could disrupt current SNF contracts with third-party suppliers, since SNFs often contract with one supplier for all medical supply products for all patients. If a SNF's exclusive supplier is not a successful bidder, the entire contractual arrangement for all necessary supplies could be jeopardized. This could create inefficiencies and increase administrative burdens – contrary to the goals of competitive bidding.

d. The Draft DMEPOS Supplier Quality Standards Do Not Fully Apply to Institutional Settings

The draft DMEPOS supplier quality standards recognize the different service requirement expected for suppliers of enteral nutrition, equipment, and supplies depending on whether the supplier is furnishing products in the home setting, in an institutional setting, or under a home health agency ("HHA") plan of care. In fact, the draft standards exempt from the extensive enteral-specific quality standards those suppliers furnishing enterals in a SNF setting or to HHA patients. Specifically, the draft standards provide that:

If the beneficiary does not receive home health services or does not reside in a SNF, the supplier shall provide qualified staff trained in enteral nutrition to implement beneficiary education, clinical monitoring, and follow-up.

Thus, SNF suppliers are not subject to the full range of quality standards. Yet, under the MMA, Congress mandates that any supplier participating in competitive acquisition must comply with the Medicare supplier quality standards – not just subsets of the standards. Specifically, Section 1847(b)(2) provides that:





- (A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:
- (i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

Likewise, in the explanation of the conference report, the conferees emphatically state that "the Secretary cannot award contracts in an area until the following conditions were met: (1) entities meet quality standards established by the Secretary. . . . " Because CMS does not apply the full range of supplier quality standards to enteral products furnished in the SNF setting, CMS likewise should not – and indeed is not authorized under the MMA – to apply competitive acquisition to enteral products furnished in the SNF setting.

e. <u>Different Service, Business Structures, and Operations Requirements in SNFs Versus Home Setting Could Compromise Bids</u>

Under the Proposed Rule, enteral suppliers could be subject to one of three different sets of quality standards: (1) the draft DMEPOS general and enteral product-specific supplier standards (including a requirement that the supplier provide qualified staff trained in enteral nutrition for beneficiary education, clinical monitoring, and follow-up) would apply to home care suppliers; (2) the draft DMEPOS general supplier standards - but not the enteral productspecific supplier standards -- would apply to suppliers serving SNF patients under arrangement with the facility; and (3) the current stringent SNF conditions of participation would apply to SNFs that bid to provide enterals to their own patients. If enteral products furnished to SNF patients are included in competitive bidding but are subject to very different quality requirements, bidders would have widely different service-related costs. It is unclear how suppliers would be able to submit realistic bids under the competitive acquisition program, since supplier's mix of services provided to beneficiaries in institutional settings versus the home care setting could be difficult to forecast. Indeed, this situation could have the unintended effect of jeopardizing access to enterals for home care patients, since suppliers might be encouraged to seek out patients that are not subject to the extensive servicing requirements for home enteral products established under the Medicare supplier quality standards – even though the nursing home patients have higher overall acuity levels. A uniform payment rate may be inappropriate in this situation. CMS needs to develop a way to determine equitable bidding and payment policies before including SNFs in competitive bidding.

3. <u>Specialized Enteral Nutrients (B4153, B4154, and B4155) are Inappropriate</u> for Competitive Bidding Framework and Should Be Excluded

Although we believe that CMS should not include any enteral nutritional products in the first round of competitive bidding, it is critical for CMS to exclude specialized nutrient products from competitive bidding (HCPCS codes B4153, B4154, and B4155).

While nutritionally-complete standard medical nutritionals are appropriate for some patients, other patients have medical conditions that require the use of specialized medical nutritional products. Products in these categories are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS,





pressure ulcers, kidney disease, pulmonary disease, Crohn's disease, diabetes, and severe burns. Only three HCPCS codes encompass this wide and diverse array of nutrients. Products within these categories are clearly not interchangeable. Feeding an inappropriate product within this category to a patient can lead to a cascade of dangerous medical complications that worsen a patient's condition, accelerate the disease process, and in some cases result in death. It would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional.

Under the proposed competitive bidding framework, a supplier would only need to furnish one product within a HCPCS code. This would not work for codes B4153, B4154, and B4155, since suppliers could choose to offer a single product in each code that helps beneficiaries with one disease state, but is useless or even dangerous for other beneficiaries that depend on other nutritional in these categories. There could even be a situation where no contract suppliers bid to supply a particular nutritional that is critical for a beneficiary's health and life.

The unique patient benefits provided by the products in codes B4153, B4154, and B4155 are detailed below:

B4153 (Enteral Formula, Nutritionally Complete, Hydrolyzed Proteins (Amino Acids and Peptide Chain), Includes Fats, Carbohydrates, Vitamins and Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

Hydrolyzed protein elemental formulas are nutritionally complete formulations that are made for patients with vastly different acute and chronic conditions, ranging from tolerance issues like malabsorption and maldigestion, to metabolically-stressed patients that are immunosuppressed and have elevated energy and protein needs. Some products in this category contain simpler nutrients, peptides, and free amino acids that use the dual protein absorption system of the gut for patients with chronically impaired gastrointestinal function. Many patients rely on these products as their sole source of nutrition, and they are the only thing the patients can digest. Other products in this category are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. Without these products, which not only contain the partially-hydrolyzed, peptide-based protein for easier absorption but are also calorically dense and high in protein, these patients would not be able to heal.

B4154 (Enteral Formula, Nutritionally Complete, For Special Metabolic Needs, Excludes Inherited Disease Of Metabolism, Includes Altered Composition of Proteins, Fats, Carbohydrates, Vitamins and/or Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

The nutritionally-complete products in this category are as different as the metabolic conditions for which they are used. These products have customized caloric distribution formulated specially to meet the needs of patients with conditions such as kidney disease and chronic kidney failure; metabolic stress resultant from acute injury, surgery or chronic disease; pulmonary disease; diabetes; HIV/AIDS; and cancer. Products in this





category are not interchangeable; in fact, substituting different products within these codes designed for different diseases could be detrimental to the patient and the condition being treated. Lack of access to any of these products can compromise the health of a patient and will impact quality of care. For instance, feeding a patient with a chronic respiratory condition (i.e., COPD) a product that is designed for someone with kidney disease who is not yet being treated with dialysis would provide a protein level that is too low as well as a carbohydrate level that is too high, causing excess carbon dioxide. Due to their lack of lung function and inability to fully respirate, this could result in toxic levels of carbon dioxide in the blood stream, leading to hospitalization. On the other hand, another product in this category specially designed for pulmonary patients would provide such patients with the clinically-appropriate levels of carbohydrates to ensure controlled carbon dioxide production and concentrated calories and protein in order to maintain low volumes of fluid consumed, a major concern for the respiratory patient. Likewise there are products in this category that are specifically designed for individuals with kidney disease being managed without dialysis. Feeding a product designed for people with diabetes to this patient would provide excessive protein and an inappropriate renal solute load that might compromise their already-impaired renal function.

B4155 (Enteral Formula, Nutritionally Incomplete/Modular Nutrients, Includes Specific Nutrients, Carbohydrates (e.g., Glucose Polymers), Proteins/Amino Acids (e.g., Glutamine, Arginine), Fat (e.g., Medium Chain Triglycerides) or Combination, Administered Through an Enteral Feeding Tube, 100 calories = 1 unit)

Products within this category are nutritionally incomplete but contain specific nutrients that address very different patient needs. For instance, one product is designed to provide an easily-digested source of carbohydrate calories for patients with increased caloric needs that cannot be consumed in food but who are on a fat-restricted diet. Another product is a therapeutic nutritional that contains a patented blend of arginine, glutamine and HMB (beta-hydroxybeta methylbutyrate) clinically proven to help build lean body mass, enhance immune response, and promote collagen synthesis in patients with advanced stages of pressure ulcers. This product also has been shown to replenish weight in the form of lean body mass or functional tissue, not fat mass, and supports immune function in patients with HIV/AIDS.

Because of the specialized nature of these products, Medicare currently requires the patient's medical record to adequately document the specific condition and the need for the specially formulated nutritional. Products in these categories represent those that are developed according to the most current nutritional recommendations, and they contain specialized formulations of ingredients as well as patented ingredients in some products. Excluding these product categories from competitive bidding would ensure beneficiary access to the appropriate specialized products.

In addition to the strong clinical reasons for excluding specialized nutritionals from competitive bidding, CMS also has authority to exclude these products under its statutory authority to exclude products that would not result in significant savings. Current Medicare spending on





products in these categories represent only 2% of total enteral nutrition spending in home setting and only 7% in all settings. (Based on 2004 CMS BESS Procedure Data). In view of the highly diversified needs of patients using these products, we do not expect competitive bidding to result in significant savings for this class of products. Since enteral nutrition sustains and supports life, and unreasonable risks could result from disruption in access, this class of products meets Congressional standards for exclusion and thus should be excluded from bidding.

If CMS nevertheless decides to include codes B4153, B4154, and B4155 at any stage of competitive bidding, CMS would need to ensure that beneficiaries in every CBA had access to products within each code that are appropriate for their distinct medical conditions or therapeutic needs. Because each product within these three codes is uniquely formulated and appropriate use is dependent on varying combinations of patient-specific factors, the development of subcategories within these codes is a complex task. We recommend that CMS work with clinical specialists to develop any such requirements and that there be an opportunity for public comment.

4. <u>Significant Clinical and Technological Distinctions of Enteral Products – The Need to Protect Access to Medically-Necessary Features</u>

Many of the HCPCS codes for enteral nutrition formulas, equipment, and supplies contain products that are not interchangeable, and in many cases have significant differences among them. Differences include a range in technology and features as well as packaging to enhance safety, and particular features may be critical to a patient's medical care. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer enteral products with such advanced, medically-necessary features unless compelled to do so. Moreover, they may choose to substitute items and base their bids on other devices and supplies not designed for enteral feeding due to concerns that their bid will not be low enough to be selected and they will lose their opportunity to serve Medicare beneficiaries in the bidding area.

The MMA provides CMS with the authority to recognize during the bidding process those products within codes that have enhanced clinical efficiency and value. Specifically, the statute provides the following:

CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

If enteral products are included in competitive bidding, CMS should exercise this authority to require that suppliers guarantee access to enteral products with certain important features that promote patient safety, as detailed below. Such features should be specified in the bidding instructions, and suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should ensure during its bid review process that any bids for enteral products include only products designed specifically for enteral feeding, since we are aware of some suppliers substituting lower-cost products (such as urinary catheters used as feeding tubes or enema bags used as feeding sets) that are not specifically designed for enteral tube feedings and that can lead to allergic reactions, corrosion of tubing, and adverse patient outcomes.





The following is a discussion of the specific product features that should be available in every CBA.

a. <u>HCPCS Code B4150 (General Purpose Formulas) & B4152 (Calorically Dense Formulas) – Access to Both Can and Pre-Mixed Packaging</u>

Nutritional products within the HCPCS codes B4150 and B4152 are available either in premixed bottles (also called "ready to hang" or "ready to use") or in cans. Ready to hang products require no handling or pouring of the product. This delivery system is important for product safety (rather than just for beneficiary convenience). Product in cans must be decanted into a feeding set or alternate container, which significantly increases the chances of contamination. Contamination refers to the introduction of bacteria into the product, which increases the risk of spoilage and can cause symptoms of food poisoning (e.g., vomiting and diarrhea), or may introduce infection. These problems may lead to dehydration or sepsis, severely compromising an already debilitated patient. A Hazard Analysis Critical Control Point ("HACCP") analysis concludes that ready-to-use products that do not expose enterals to the air during assembly have lower contamination rates than open systems. HACCP's "Guidelines for preventing healthcare-associated infections during enteral feeding in primary and community care" therefore recommend that "Wherever possible pre-packaged, ready-touse feeds should be used in preference to feeds requiring decanting, reconstitution or dilution," and the "system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube."22 Beneficiaries, their clinicians, and caregivers need access to ready to hang products as appropriate; in fact, some clinical care protocols require the use of such products. Accordingly, CMS should ensure beneficiary access to ready to hang product by requiring suppliers to guarantee access to and availability of ready to hang products within the B4150 and B4152 HCPCS codes.

To ensure patient access to ready to hang packaging, CMS should require suppliers to specify on the bidding sheet that they will supply both can and ready to hang packaging for products in codes B4150 and B4152, and provide such products to the beneficiary in the packaging specified by the patient's health care professional.

b. <u>HCPCS Code B9002 (Enteral Feeding Pump w/Alarm) – Access to Pumps with Automatic Flush Feature, that are Ambulatory, have Anti-Free Flow Feature, and Lock-Out Option</u>

CMS should require that suppliers guarantee access and availability of enteral pumps with essential features to meet their specific medical needs. The features include:

Final Guideline: Prevention of healthcare-associated infections in primary and community care, June 2003.





- (1) <u>Automatic Flush</u>. This feature is necessary for patients who need small bore feeding tubes such as jejunostomy tubes and are prone to tube clogging (<u>i.e.</u>, patients who use multiple medicines and patients who need to have residuals checked frequently).
- (2) <u>Ambulatory</u>. This feature is necessary to allow patients who are not bed ridden to move around with their pump (<u>i.e.</u>, get up to use the bathroom).
- (3) Anti-free flow. This safety feature prevents inadvertent free flow of product that could result in overfeeding and other inadvertent adverse events.
- (4) <u>Lock-out option</u>. This safety feature prevents tampering with pump settings to prevent overfeeding or underfeeding. This feature is necessary for patients with mental disabilities such as Alzheimer and patients with small children in the home.

CMS should specify in the bidding instructions that enteral suppliers must furnish a range of product options within HCPCS code B9002 that include an automatic flush feature, are ambulatory, have an anti-free flow feature, and a lock-out option, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features.

c. <u>HCPCS Code B4086 (Gastrostomy/jejunostomy tube, any material, any type, standard or low profile) – Access to Safety Features, Designed for Enteral Use</u>

Feeding tubes vary widely in terms of their dimensions, composition, ability to prevent clogging or contamination, among other important features. Beneficiaries need access to the tubing selected by their provider to be safe and medically-appropriate. CMS should ensure through the bidding process that any supplier bidding on enteral tubing agree to furnish tubing with the following features:

- (1) Polyurethane and silicone. Tubes may be constructed of various materials, ranging from polyvinyl chloride ("PVC") and latex to polyurethane and silicone tubes. PVC and latex tubes are cheaper than polyurethane and silicone tubes, but they can stiffen and erode from contact with digestive juices, are associated with allergic reactions, and often are not designed specifically for enteral feeding (i.e., some suppliers substitute with foley catheters designed for bladder drainage) Polyurethane and silicone tubes, while more expensive, are the most biocompatible and appropriate for patient care
- (2) Radiopaque material. This is necessary to help ensure proper placement of a tube into the stomach or small intestine and x-ray confirmation of tube placement.





- (3) Weighted tips. This is necessary to lessen the risk of improper placement and backward migration of the tube, to which some patients may be prone.
- (4) Eyelet design, flow-thru tips. This feature is necessary to reduce tube clogging that can result in a premature need for tube replacement.
- (5) Y-port/Interlocking connectors. This is necessary to provide an additional port used for flushing the tube and for administering medications without the need to disconnect the feeding set and tube. This helps minimize the risk of touch contamination, which is essential to quality patient care and safety. Another important part of the Y-port connector is the cap that interlocks with the O-ring on the feeding set. An interlocking feature minimizes leakage and potential for inadvertent or accidental separation, which could result in a patient not getting fed appropriately.
- (6) Skin disk or external retention hub at the surface of the skin. This is necessary to maintain tube position, decreasing the chance of tube migration inward and minimizing leakage of gastric contents around the tube.
- (7) <u>Internal bumper.</u> This is a necessary feature that secures the tube up against the gastric wall to minimize unwanted changes in position and leakage of gastric contents.

CMS should specify in the bidding instructions that enteral suppliers must furnish products within HCPCS code B4086 that are composed of polyurethane and silicone; include radiopaque material; and/or have the following features: weighted tips; include eyelet design/flow-thru tips; Y-port/interlocking connectors; skin disk or external retention hub; and internal bumper. Suppliers must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding.

d. HCPCS Code B4081 (Nasogastric tube with stylet) & B4082 (Nasogastric tube without stylet) – Access to Polyurethane Tubes, With or Without Stylet

CMS should require that suppliers guarantee access and availability of nasogastric tubes with specific features to ensure beneficiaries have access to tubes that will meet their specific medical needs. Such features within HCPCS code B4081 and B4082 include:





- (1) Polyurethane tubes. Soft, flexible material necessary for both patient comfort and to decrease tube-related complications when placing a tube through the nasal passage for enteral feeding. Tubes made of any other substance (i.e., PVC) become brittle with repeated use, resulting in unnecessary discomfort and tube-related complications for the patient.
- (2) <u>Nasoenteric tube with stylet</u>. This is necessary for placement of a soft and flexible small bore tube. The stylet provides the temporary stiffening of the tube during this invasive placement procedure.

CMS should specify in the bidding instructions that enteral suppliers must furnish nasogastric tubes (B4081 and B4082) comprised of polyurethane, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding. Likewise, CMS should require suppliers to furnish nasogastric tubes with or without stylets as specified by the patient's health care professional.

e. <u>HCPCS Code B4035 (Pump Supply Kit)</u>, B4034 (Syringe Supply Kit) and B4036, (Gravity Supply Kit) -- Access to Appropriate Feeding Supply Kits

Manufacturers specifically design enteral feeding supply kits (pump, syringe and gravity) to connect to feeding pumps (HCPCS code B9002) and feeding tubes (HCPCS codes B4086, B4081 and B4082) as an integrated system for enteral nutrition delivery. These designs include special interlocking connectors that eliminate the need to tape connectors and decrease the likelihood of inadvertent or accidental separation from the feeding set, which can result in underfeeding and increased risk of leakage and contamination. Manufacturers research and test the use of these integrated systems to ensure both patient safety as well as ease of use, which is particularly important for patients and caregivers in the home setting.

CMS should specify in its bidding instructions that suppliers must use supply kits that are manufacturer-researched and tested to be appropriate for use in an integrated enteral feeding system. Moreover, if a supplier begins servicing a beneficiary that already owns or rents an enteral feeding pump, the supplier must provide the beneficiary with the appropriate supply kit for the beneficiary's specific equipment.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

<u>Abbott Recommendation:</u> CMS should protect beneficiary safety and choice by implementing, at a minimum, the Medicare Part D proximity measures when determining capacity needs for CBAs.

Section 1847(b)(4)(A) provides that in determining the number of suppliers necessary for a CBA, the Secretary shall:





... take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

We are concerned that CMS's proposal to provide as few as two suppliers in a CBA would be insufficient to meet this statutory requirement and to protect beneficiaries who rely on enteral nutrients. Enteral nutrients are the sole source of a beneficiary's nutrients and they play a life-sustaining role in a beneficiary's health care regimen. Since enteral nutrients are the food supply for these beneficiaries, they simply cannot wait for days to receive service from a restricted number of winning suppliers. These beneficiaries also need to have a variety of suppliers in close proximity if an emergency situation arises, such as if an immediate change in products is necessary to sustain life.

Likewise, the delivery of enteral nutrition involves intense supplier services for and consistent routine monitoring of patients using enteral equipment, as discussed above. Beneficiaries using enteral products are subject to a wide range of serious and even life-threatening complications from tube feeding. The complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies, and suppliers need to be in close proximity to their patients to immediately address complications.

In addition, CMS should respect the close nature of the relationship between the beneficiary and the supplier, and ensure beneficiaries have a choice in which supplier will enter their home to delivery enteral nutrition products. It is critical that these patients feel comfortable with the supplier that will enter their home and stand bedside to educate them on steps to resolve common feeding problems, use, storage, and maintenance of all equipment and supplies; including cleaning the gastrostomy/jejunostomy site and recognition and appropriate response to various types of complications.

Due to the critical nature of enteral nutrition and the need to have suppliers in close proximity to their patients, we recommend that CMS implement as a minimum standard the Medicare Part D proximity measures when selecting suppliers for a CBA. As noted above, the Medicare Part D proximity standards require drug plans to establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

Application of the Medicare Part D proximity standards to home care suppliers under the DMEPOS competitive bidding program would help ensure suppliers are close enough in proximity to their patients to service their enteral nutrition needs without an unreasonable travel delay. As in the Part D program where only retail suppliers count toward meeting this





proximity standard, under Part B only home medical equipment suppliers should count towards this minimum number. Likewise, if CMS decides to allow mail order suppliers to bid, those mail order suppliers should <u>not</u> count towards the minimum number of suppliers that CMS is establishing in each CBA, since the draft DMEPOS quality standards limits the services mail order suppliers may provide to beneficiaries.

It is also important for CMS to consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful Medicare bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly patients requiring enteral nutrition. In addition, suppliers that provide enteral products usually have a larger portion of non-Medicare patient populations (i.e., pediatric patients). If there is insufficient DME supplier interest in bidding to supply enteral items for the Medicare population, it could have a negative impact on non-Medicare beneficiary access to critical enteral nutritional items and services.

D. <u>Bidding Requirements/Enteral Nutrition Equipment and Supplies</u>

<u>Abbott Recommendation</u>: <u>If</u> enteral products are included in competitive bidding, CMS should establish separate single payment amounts for enteral nutrients and enteral supplies. CMS should not reduce rental payments for enteral equipment in months 4 through 15.

1. Single Payment Amounts

In the discussion of enteral nutrition equipment and supplies, CMS states that "Based on the bids submitted and accepted for new items, we would calculate a <u>single payment amount for purchase of enteral nutrients and supplies.</u>" This language could be read to indicate CMS is contemplating a bundled payment for both nutrients and supplies, although the proposed regulatory text appears to indicate that CMS would establish a single payment amount for purchase of enteral nutrients and a separate single payment amount for supplies. We seek to confirm that if enteral products are included in competitive bidding, CMS intends to establish <u>separate</u> single payment amounts for each enteral nutrient and supply HCPCS code – rather than a bundled payment amount for enteral nutrients and related supplies.

2. Reduction in Rental Payments

We also are concerned about CMS's proposal to reduce rental payments for enteral equipment in months 4 – 15 from 10 percent of the purchase amount (as is the case under current Medicare fee-for-service rules) to 7.5 percent of the single payment. Due to the service-intensive nature of providing enteral nutrition and the possible increased costs that new quality standards requirements will impose on suppliers, reducing the rental payment formula in addition to reducing payment through the bidding process could further impede suppliers' ability to provide high-quality products and services to Medicare beneficiaries.





E. <u>Grandfathering of Suppliers [Payment Basis]</u>

<u>Abbott Recommendation</u>: If CMS includes enteral equipment in competitive bidding, CMS should include enteral equipment in the grandfathering process.

We support CMS's proposal to allow grandfathered suppliers to continue to furnish rental items under existing rental agreements and to allow accessories and supplies used in conjunction with grandfathered rental DME to be furnished by grandfathered supplier. However, it appears under the technical regulatory language that the provision would not apply to rented *enteral* feeding pumps. It appears that the omission of enteral pumps from the grandfathering provision is an oversight since enteral pumps technically fall under the orthotics and prosthetics benefit category, rather than the DME category. Moreover, CMS provides in the CMS Medicare Claims Processing Manual that "Payment policies for these pumps generally follow the rules for capped rental items." Thus it would be consistent for CMS to apply the grandfathering process to enteral feeding pumps just as it does to capped rental DME items.

Beneficiaries using enteral equipment should have the benefit of this provision, particularly because of the importance of continuity of care for these clinically-complex patients and their intensive service needs. We therefore respectfully request that CMS specifically apply the grandfathering provision to suppliers of enteral nutritionals, equipment, and supplies in the final rule.



Medicare Claims Processing Manual, Chapter 20, section 30.7.1.



III. Other Competitive Bidding/Payment Reform Comments

A. Physician Authorization/Treating Practitioner

<u>Abbott Recommendation</u>: We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.

CMS proposes to allow a physician or treating practitioner to prescribe a particular brand of an item or mode of delivery of an item if he or she determines that it would avoid an adverse medical outcome for the beneficiary, and the supplier would be required to furnish the specified brand or mode of delivery. We strongly support this provision. As we have previously noted, blood glucose monitoring products and enteral products within a particular code are not interchangeable. In many cases, substitution of enteral nutrition or blood glucose monitoring products other than those specifically prescribed by the physician could lead to adverse medical outcomes. We therefore agree with CMS that physicians and practitioners need to be able to prescribe the most clinically-appropriate product for their patients, and that to prevent interference with the practice of medicine, suppliers should be prohibited from switching products without written physician authorization.

B. Conditions for Awarding Contracts/Quality Standards & Accreditation

<u>Abbott Recommendation</u>: We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.

Quality standards are key to protecting beneficiaries in CBAs, particularly for beneficiaries with diabetes and those that rely on enteral nutrition because of the often complex clinical management of the beneficiaries' medical conditions and the critical need for ongoing beneficiary support. Quality standards are the main safeguard against suppliers submitting unreasonably low bids and then providing inferior items and/or poor beneficiary service. However, to date CMS has released only a draft contractor report on the quality standards.

CMS staff have indicated that the agency received more than 5000 comments on the draft standards, and that substantial revisions would be made in the final version. We are concerned that CMS has not provided sufficient detail regarding the proposed supplier quality standards to allow informed public comment, as is required under the Administrative Procedure Act. CMS's notice must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making. See Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549 (D.C. Cir 1983) (holding that the EPA did not give adequate notice that it might issue a strict interim lead-content limit for leaded gasoline produced by certain small refiners and this procedural error was reversible error). CMS therefore should keep open the comment period on the Proposed Rule until after the final quality standards are issued and the public has sufficient time to review those standards and their interaction with the competitive bidding framework.





Moreover, in light of the importance of the quality standards to the whole competitive bidding program, we recommend that CMS issue the revised quality standards in proposed form and allow another comment opportunity on the quality standards. Suppliers also will need time to develop systems and train personnel to comply with these standards and to become accredited. Given the delay in releasing final quality standards, it will be difficult for suppliers to come into compliance in time for competitive bidding to be implemented in 2007. CMS should not implement competitive bidding until appropriate quality standards are in place and a sufficient number of suppliers are accredited to provide adequate services to meet beneficiary demand.

C. <u>Conditions for Awarding Contracts/Determining the Pivotal Bid, & Determining Single Payment Amounts for Individual Items</u>

<u>Abbott Recommendation</u>: We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean). CMS should exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians) and mail order suppliers when establishing pivotal bids and single payment amounts. CMS should only include bids of suppliers that have been accredited. CMS should establish safeguards to prevent suppliers from skewing pivotal bids and single payment amounts by bidding unrealistically low prices and then dropping out of the program.

1. Pivotal Bid and Payment Methodologies

It is critical that CMS establish a bid selection process that is equitable and that will result in payment amounts that are sustainable and compatible with access to quality care for Medicare beneficiaries. We are concerned that under the Proposed Rule, bid prices could be distorted by extremely low bids for a particular product (there is little incentive to bid very high prices since it is unlikely such a bidder would be selected as a contract supplier). CMS would achieve pricing that is more reflective of the marketplace if it did not include in its calculation of pivotal bids or single payment amounts outlier bids based on two standard deviations of all bids submitted. Likewise, CMS should weight bids by supplier capacity to prevent suppliers that expect to offer few items from having as much weight as major suppliers in an area and possibly distorting payment amounts.

Moreover, by using a median of winning bids to set the single payment amount, CMS is proposing an untested methodology under which half of "winning" bidders would actually be paid less than the amount they bid. It is doubtful that half of the winning suppliers will be willing or able to accept payment amounts below their bid price, particularly since there is such a strong incentive under the bidding framework to bid as low as possible to have the best chance of continuing to serve Medicare beneficiaries. This could have a dramatic impact on the number of suppliers that actually decide to participate in the program once the single payment amounts are announced, and subsequently could adversely impact convenient beneficiary access to suppliers. It also appears that setting payment rates at a fairly arbitrary level does not comport with the free-market dynamics that Congress envisioned when establishing competitive bidding. We therefore recommend that CMS use the first phase of competitive bidding to test alternative payment methodologies, such as using the mean or a





weighted mean, in various CBAs. This would provide important information to CMS on which to build when the program is expanded in 2009.

2. <u>Inclusion of Limited Service, Mail Order, or Unaccredited Bidders</u>

There also is a danger that the pivotal bids and single payment amounts could be distorted by the inclusion of bidders providing a restricted set of services, by bidders who are not accredited, or by "low-ball" bidders who can simply leave the program if not satisfied with the ultimate reimbursement rates. This in turn could deny legitimate suppliers the ability to participate in the program, render it difficult to establish sufficient supplier capacity, and ultimately diminish the availability of DMEPOS items and services for beneficiaries.

CMS contemplates including all bids submitted by all suppliers when determining the pivotal bid. CMS then would consider all supplier bids that are at or below the pivotal bid when determining the single payment amount for an item. However, CMS is proposing separate requirements for some bidding suppliers that would impact their cost of doing business and could distort bidding amounts.

For instance, CMS proposes that physicians who are also DMEPOS suppliers would not be required to furnish DMEPOS items to beneficiaries in competitive bidding areas who are not their patients if they choose not to function as commercial suppliers. Likewise, CMS states that a SNF would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elects not to furnish as a commercial supplier. On the other hand, non-physician and non-SNF suppliers must agree to furnish competitively bid items to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. Because commercial suppliers would not be permitted to select or restrict their customers, as a SNF or physician could, they would have very different costs of doing business. Moreover, SNFs would not be responsible for complying with the full set of DMEPOS quality standards, as previously discussed, which again would widen the differences in their costs compared to commercial suppliers. SNF and physician bid prices thus should not be directly compared to the bids of retail suppliers. The most equitable policy would be to exclude SNF and physician bids from consideration when determining the pivotal bid and the single payment amount.

Similarly, as noted previously, CMS should not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. Indeed, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because CMS is imposing narrower service-related costs on mail order suppliers, it would be unreasonable and unfair to include their bids in the determination of pivotal amounts or single payment amounts. Including mail order suppliers – with their reduced responsibilities and therefore reduced costs — in the same bidding pool as retail suppliers also would distort the median bids and make it more likely that small retail suppliers would have to accept a single payment amount that is below the amount that they bid.

In addition, compliance with quality standards – promoted through supplier accreditation – is a significant factor in determining bid amounts. The costs associated with such compliance are unknown since CMS has not yet released final quality standards. CMS states that it will not award a contract to an entity unless the entity meets applicable quality standards, but CMS





may grant a grace period for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, CMS would suspend or terminate the supplier contract. CMS also states that it would ensure that suppliers meet quality and financial standards prior to arraying the bids for determination of the pivotal bid. However, CMS is silent on whether suppliers benefiting from a grace period would be included in the pivotal bid determination or single payment amounts. Because such suppliers have not demonstrated their compliance with supplier quality standards, and because they ultimately may not be accredited or participate in the bidding program, CMS should not consider their bids when setting the pivotal bid or single payment amounts.

Moreover, the proposed rule is silent on whether each individual retail location of a chain supplier will be allowed to submit a bid for the same product category in a particular CBA if each location has its own supplier number. We are concerned that allowing one parent company to essentially bid multiple times — either at the same or different bid prices — would distort the bidding process by overly weighting one company's bids and result in skewed payment amounts. Moreover, due to the parent company's contracting arrangements, it could potentially limit the range of items available to beneficiaries and clinicians within a particular HCPCS code. CMS therefore should clarify in the final rule that even if a corporate entity has multiple supplier numbers, it may submit only one bid for a product category in a CBA.

3. <u>Impact of Winning Bidders Dropping Out of Program</u>

Finally, we are concerned that suppliers may bid prices below which they actually can afford to supply covered items in the hopes of being a winning bidder and in the expectation that prices will be brought up by other, higher bidders. If the single price ends up insufficient for such suppliers, they may simply leave the program. Yet the unrealistic, unsustainable prices they submitted would continue to have an impact on other suppliers through the artificially low payments for the three years of the contract. Such unrealistically low prices could make it difficult to attract new suppliers to fill the capacity resulting from the low-ball bidder leaving the program. Under the Proposed Rule, there is little drawback to a supplier adopting such a low-ball strategy, despite the impact it has on payment levels, capacity calculations, and beneficiary service. CMS should consider more effective ways to prevent such manipulation of the system.

We also recommend that CMS monitor reductions in the number of suppliers for a particular item, which could indicate an unrealistic and unsupportable payment amount (notwithstanding CMS's plans to try to recruit more suppliers to replace those that leave the program). If reductions in supplier capacity reaches a certain threshold, such as a 10 percent difference in the original winning suppliers, CMS should rebid the products rather than continue to attempt to find suppliers willing to accept a price that clearly does not reflect what the market as a whole can support.

D. Payment Basis: Authority to Adjust Payments in Other Areas

Abbott Recommendation: We recommend that CMS not extend pricing developed in competitive bidding to any other areas until a complete impact analysis can be performed and mandated reports have been submitted. After such analysis has been completed, CMS should issue a proposed rule which would offer the public an





opportunity to comment on standards for any extension of pricing from competitive bidding in other areas.

CMS proposes to exercise its authority to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in CBAs. However, the agency has not yet announced a detailed methodology for such a process.

Given that the scope of this provision would extend far beyond the limited number of competitive bidding areas, CMS should establish this policy through a separate rulemaking that spells out the criteria for making fee schedule adjustments. We recommend that CMS adopt as a minimum standard the procedural safeguards included in the final inherent reasonableness rule.²⁴ which provides among other things that:

- Payments may not be reduced by more than 15 percent in a given year (except in extraordinary situations and after additional procedural safeguards are observed);
- CMS must publish in the Federal Register proposed and final notices announcing the new payment limits prior to adoption;
- If the dollar impact of an adjustment exceeds \$100 million in any one year, CMS must publish in the Federal Register an impact statement, including an analysis of the effect of quality of care, access issues, and the financial viability of suppliers in the marketplace;
- If CMS makes adjustments that have a significant effect on a substantial number of small entities, it must publish an analysis in compliance with the Regulatory Flexibility Act;
- In no case may the effective date of an adjustment be sooner than 60 days after publication of the final notice; and
- CMS must ensure the use of valid and reliable data.

Moreover, we recommend that CMS not apply competitive bidding prices in other areas until the results of the first phase of competitive bidding are fully assessed. Specifically, CMS should not extend competitive bidding prices beyond CBAs until: (1) the Government Accountability Office ("GAO") issues its report on the impact of competitive acquisition on DME on patients, suppliers, and manufacturers of medical equipment, and (2) the Secretary submits its report to Congress on program savings, access to and quality of items and services, and beneficiary satisfaction. It would be imprudent to extend the reach of competitive bidding prices without the benefit of the Congressionally-mandated analyses, which will assess how competitive acquisition affects beneficiary access to DMEPOS along with product quality and services related to DMEPOS.



^{24 67} Fed. Reg. 76,684 (December 13, 2002).



E. Other Competitive Bidding Issues

1. Education and Outreach

We commend CMS for proposing extensive supplier and beneficiary outreach and education initiatives as part of the competitive bidding program. Such efforts will be an important component in ensuring the smooth implementation of the new distribution and payment structure. We also urge CMS to include physicians and other clinicians in these outreach and education efforts, given their important role in prescribing the most appropriate products for their patients.

2. <u>Monitoring and Complaint Services for the Competitive Bidding Program</u>

We support CMS's plans to establish a formal complaint monitoring system to address complaints in each CBA. We believe that the information collected will be particularly helpful to CMS as it prepares to expand competitive bidding to additional areas in subsequent phases of the program.

We recommend that CMS include in its complaint monitoring system the collection of brand-specific information on medical complications related to competitively-bid equipment, especially for blood glucose monitoring products and enteral products if they are included in competitive bidding because of the potential for complications with these items. Moreover, CMS should collect data on suppliers that do not successfully furnish particular brands of equipment specified by practitioners. We recommend that CMS release timely reports on the results of its complaint monitoring system to inform public dialogue and analysis regarding the competitive bidding program and to ensure adequate data is available to guide development of subsequent phases of the program.

3. Miscellaneous Codes

CMS does not discuss how it would consider miscellaneous equipment and supply codes in competitive bidding. Because miscellaneous codes can encompass a wide range of products at a wide range of prices, and because suppliers would not be able to predict which brands of miscellaneous products they would need to supply during a three-year bidding cycle, we recommend that CMS exclude miscellaneous codes from competitive bidding.

F. Gap Filling Payment Methodology

Abbott Recommendation: CMS should issue a separate rulemaking to clarify and refine the gap fill pricing methodology, and should not adopt "functional technology assessments" as currently proposed. The new rulemaking should set forth the possible criteria, evidentiary standards, and procedural safeguards CMS proposes to use in performing functional technology assessments.

CMS is proposing significant revisions to its pricing policy for DMEPOS fee schedule amounts. Instead of a "gap fill" process that has been used since 1989, CMS is proposing to base payment for new items in part on a new "functional technology assessment" process, which takes into account one or more of the following factors: (1) functional assessment; (2) price





comparison analysis; and/or (3) medical benefit assessment. CMS also is proposing to use the new technology assessment process to adjust prices already established using the gap-filling methodology. Further, CMS indicates that these analyses also will be used in the HCPCS coding process and potentially the Medicare coverage process.

We are concerned about CMS raising this major pricing reform (and potentially coding and coverage policy changes) in the context of the DMEPOS competitive bidding rule, since the scope of this proposed policy goes far beyond the statutory competitive bidding authority. Gap-filling is an important and complex process with an impact on thousands of medical products, and it deserves appropriate attention apart from the competitive bidding rule. Given the impact the proposed pricing policy would have on new and established technologies and the significant changes already planned in 2007 as a result of competitive bidding, CMS should not adopt any changes in the gap filling methodology until at least 2008.

If CMS decides to pursue this policy, a separate, detailed proposed rule should be issued with an opportunity for public comment. CMS would need to provide much greater specificity than it has in the context of the proposed competitive bidding rule, since CMS has failed to define key concepts and left important questions unanswered, such as:

- What CMS means by "significantly improved clinical outcomes";
- What clinical data CMS would review:
- How the agency would determine what products are "similar" for price comparison purposes;
- What timelines of data would be utilized in such analyses;
- How CMS would define and determine "effectiveness";
- What procedural safeguards CMS would employ in making functional assessment determinations, such as how the agency would notify manufacturers and beneficiaries regarding pending decisions and what opportunities would be made available for submitting evidence and comments:
- What procedural and evidentiary standards carriers would be required to follow in making such functional assessments;
- What the relationship would be regarding the functional assessment process and CMS's current coverage process, as it appears the proposed policy would duplicate a number of functions of the CMS coverage group;
- How the process would interact with the current HCPCS coding process, including the
 potential impact on transparency of coding decisions (<u>e.g.</u>, public meetings and
 notification of pending decisions); and
- How CMS would ensure that its new policies would not further extend the timelines for coding, coverage, and reimbursement decisions.





Moreover, if CMS considers changes to the gap-filling policy in the future, CMS should ensure, through Open Door Forums and other means, that suppliers, clinicians, the medical technology community, and beneficiaries are fully consulted on potentially dramatic changes in Medicare coverage, coding, and reimbursement policies.

We recommend that CMS proceed cautiously in this area, given its potentially significant impact on coding, coverage, and payment policy, and ultimately is effect on beneficiary access to innovative medical technologies.

G. Regulatory Impact Analysis

We are concerned that CMS may underestimate the impact on of the Proposed Rule on beneficiary access to their choice of supplier. While CMS acknowledges that "competitive bidding may result in some beneficiaries needing to switch from their current supplier if their current supplier is not selected for competitive bidding," CMS states that it expects this need for switching to be "minimal." We believe this severely underestimates the impact of the reduced choice of supplier. CMS expects only half of bidding suppliers to be selected, which undoubtedly will result in restricted beneficiary choice of suppliers. Moreover, only limited types of DMEPOS are eligible for the grandfathering provision. We believe CMS should reassess its estimates on beneficiary access and ensure that the final rule promotes the widest beneficiary choice of suppliers.

We also seek to ensure that CMS provide realistic estimates of the administrative costs associated with the competitive bidding program, since it will be essential to determine the extent to which administrative costs offset the savings to the program resulting from reduced Medicare reimbursement rates. CMS expects bidding-related costs to suppliers to reach over \$36 million in just the first round of bidding, and that CMS and its contractors will have approximately \$1 million in immediate fixed costs for startup and system changes. CMS also will incur maintenance costs and bid solicitation and evaluation costs, but the agency does not quantify those costs because those costs "will ultimately depend on number of suppliers that chose to submit bids." We believe that CMS should provide more constructive information on these expected costs.

Moreover, we believe that any evaluation or estimates of Medicare program savings should include an analysis of offsetting increases in hospital and other Part A costs associated with adverse clinical outcomes related to competitive bidding. Specifically, CMS should compare Part A spending in CBAs to spending in comparable areas that are not subject to competitive bidding to determine if the new program is having unintended, adverse impacts requiring the need for hospital care. Such findings should be made publicly available.

Likewise, as part of its initial and ongoing impact analyses, we recommend that CMS monitor the impact of competitive bidding on Medicaid beneficiaries and privately-insured individuals. We are concerned that many suppliers who are not winning Medicare bidders will not be able to continue supplying DMEPOS in competitive bidding areas, which would affect the availability of needed medical equipment and supplies for the non-Medicare population.





In conclusion, we believe that enteral and diabetes products are poor candidates for the first round of the competitive bidding program, as detailed above, and should qualify for exclusion. If, however, CMS seeks to subject enteral and diabetes products to competitive bidding in any later phases, then we urge CMS to adopt the protections and qualifications as described in our comments above.

We appreciate your commitment to developing the competitive bidding program in a way that protects beneficiaries and promotes efficiency in the Medicare program. We trust that our comments provide constructive information for CMS to consider in adopting the final competitive bidding rule. Given the importance of this issue to beneficiaries with diabetes and those that rely on enteral equipment, we would appreciate the opportunity to meet with your staff to discuss the impact on these two specific patient groups and the special operational issues that would need to be adopted to safeguard their medical care. I will be in touch with your office to arrange a meeting. In the meantime, please feel free to call on me if you would have any questions.

Sincerely,

Virginia Tobiason Senior Director

Corporate Reimbursement

Virginia Teleason



Tara A. Cortes, RN, PhD
President and CEO

June 30, 2006

Mark McClellan, MD, Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Att: CMS-1270-P, Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-8013

Re: Low Vision Aid Exclusion

Dear Dr. McClellan,

On behalf of millions of Americans who are visually impaired, Lighthouse International is requesting reconsideration of the Centers for Medicare and Medicaid (CMS) proposed rule to exclude coverage for low vision aids/assistive technology devices that that are critical to maintaining independence for people with impaired vision, particularly older adults.

Lighthouse International was founded over 100 years ago, and is a leading low vision/vision rehabilitation resource for people who are at risk for, or experiencing, uncorrectable vision loss due to age-related eye diseases such as macular degeneration, diabetic retinopathy, glaucoma and cataracts.

There are 16.5 million Americans age 45+ who self-report vision impairment. This number is rising dramatically with our aging population, and is expected to balloon to 20 million by 2010. The incidence of self-reported vision impairment, which is among the most disabling conditions for older adults, rises dramatically with age, from approximately 1 in 6 age 45+ to 1 in 4 age 75+. In addition to the millions of aging baby boomers who will be facing vision impairment in record numbers, Americans over 85 comprise the largest growing segment of our population, making vision impairment and its disabling consequences one of the leading public health concerns of our day.

Low vision aids are prescribed by low vision doctors as part of the comprehensive vision rehabilitation process designed to restore functioning for people who are visually impaired. Low vision care is a treatment modality and devices are part of the complete continuum of care. Ranging from strong reading lenses and magnifiers to electronic magnification systems (closed-circuit television systems known as CCTVs) and other low vision technologies, these

The Sol and Lillian Goldman Building 111 East 59th Street, New York, NY 10022-1202 Tel: (212) 821-9200 Fax: (212) 821-9701 TTY: (212) 821-9713 www.lighthouse.org

are critically important tools that enable people who are visually impaired to read, write, cook, and remain safe and independent. For example, without a low vision device, people with impaired vision would not be able to read medication labels, which would have untold disastrous consequences. These aids are essential to ensuring function, health and quality of life for older Americans living with impaired vision and, oftentimes, an increasing number of co-morbid conditions.

The cost of some low vision devices is prohibitive, especially for older Americans on fixed incomes. Without CMS coverage, an alarming number of people will be at risk for medical complications, accidents and injuries, further straining our overtapped healthcare system. It is striking to note that today, vision impairment is one of the four leading causes of loss of independence among older adults; lost independence due to all causes costs the US over \$26 billion in medical and long-term care each year.

We can not stress strongly enough the need to distinguish between routine eyeglasses that correct refractive errors, which are not covered, and low vision devices that do not correct refractive errors, but enlarge or redirect images for people with uncorrectable vision loss, as part of a comprehensive vision rehabilitation program. This issue has been delineated so effectively by the American Academy of Ophthalmology: "These devices do not correct the visual acuity through the correction of refractive errors; they are prosthetics that replace part of the function of a non-functioning organ."

Lighthouse International joins the Academy and other leading organizations like the American Foundation for the Blind in urging that CMS reconsider its proposed rule to bar coverage of low vision devices that would have a devastating effect on the lives of millions of Americans.

We welcome the opportunity to contribute to the development of policy that would distinguish between conventional eyeglasses and low vision devices/assistive technologies, and appreciate the opportunity to comment on the CMS proposed rule.

Sincerely,

Tara A. Cortes, PhD, RN

President and CEO

note attempted to e-mil on 6/30 but can system down.

ARC - Lightman det

Error Executing Database Query.

[Macromedia][Oracle JDBC Driver][Oracle]ORA-01704: string literal too long

Please try the following:

- Enable Robust Exception Information to provide greater detail about the source Settings, and select the Robust Exception Information option of errors. In the Administrator, click Debugging & Logging > Debugging
- Check the ColdFusion documentation to verify that you are using the correct
- Search the Knowledge Base to find a solution to your problem.

Browser

Mozilla/5.0 (Windows; U; Windows NT 5.1; en-US; rv:1.8.0.4) Gecko/20060508 Firefox/1.5.0.4

Address Remote

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Referrer

http://www.accessdata.fda.gov/

Date/Time

30-Jun-06 02:33 PM

1200 G Street NW, Suite 400 Washington, DC 20005-3814

Tel: 202 783 8700 Fax: 202 783 8750 www.AdvaMed.org





Ann Marie Lynch
Executive Vice President
Payment and Health Care Delivery

Direct: 202 434 7203 alynch@advamed.org

June 30, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

File Code CMS-1270-P: Comments Related to Proposed Rulemaking re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006).

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this comment letter to the "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule). AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goals of assuring beneficiary access to services, and continues to take a keen interest in ensuring access to high quality DMEPOS related items and services. As noted in both our April 4, 2006 and May 12, 2006 letters to CMS, AdvaMed and its members are deeply concerned regarding the process for implementing competitive acquisition (competitive bidding) and the development of new quality

standards for DEMPOS suppliers. The Proposed Rule would implement competitive acquisition for certain covered items of DMEPOS in accordance with sections 1847(a) and (b) of the Social Security Act. CMS notes that "The DMEPOS supplier industry is expected to be significantly impacted by this rule when finalized," and estimates that about 50 percent (approximately 8,500 small suppliers in the ten competitive bidding areas) would lose all of their Medicare DMEPOS business. As outlined later in this letter, AdvaMed believes that CMS should take steps to relieve the negative impact on small suppliers.

We appreciate the enormity of CMS's task in implementing competitive bidding, and we know that CMS staff are fully dedicated to the task at hand. However, AdvaMed believes that there are a number of key issues that need to be addressed before any aspect of competitive bidding can be implemented. As noted in our previous letters of April 4 and May 12, a key component of CMS's implementation of competitive bidding under the Proposed Rule involves the application of 'quality standards' for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. The Proposed Rule also contains requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers participating in the competitive bidding program

AdvaMed has noted in previous correspondence with CMS that CMS has not finalized its quality standards, having to date released only <u>draft</u> standards on September 23, 2005. While CMS accepted public comments on those standards, there has been no publication of final standards notwithstanding that the quality standards are an integral part of the Proposed Rule.

As we noted in our previous letters, stakeholders are currently in the untenable position of having to make substantive analysis and comment on the incomplete parameters contained in the Proposed Rule. The proposed quality standards are exhaustive and may include performance management requirements to ensure development, implementation, monitoring, and evaluation of policies, procedures, and products to enable suppliers to maintain compliance with regulatory requirements and CMS policy instructions. We do not believe that CMS should proceed with the implementation of competitive bidding (as described in the Proposed Rule) until there has been a formal notice and comment process sufficient to allow stakeholder assessment of the quality standards within the context of competitive bidding

As we have stated in previous correspondence, we believe CMS should hold the comment period in abeyance until it issues the supplier quality standards. Stakeholders would then have the opportunity to evaluate the quality standards, a critical part of competitive bidding, in the appropriate context with competitive bidding in a proposed rule prior to CMS's issuance of a final rule. If CMS does issue a Final Rule absent the release of quality standards, we believe that the rule should be issued only as an interim final rule, and that a new proposed rule should be issued at the time the quality standards are released. The new proposed rule would allow stakeholders to comment on

competitive bidding within the appropriate context of supplier quality standards and definitive parameters for implementation.

Before proceeding with our specific comments below, we would like to emphasize that any competitive bidding program developed by CMS should include the following:

- Beneficiaries should be guaranteed access to the most appropriate technology.
- Competitive acquisition should support technology innovation and ensure that beneficiaries are the recipients of the latest technological advances.
- The entire competitive bidding process should be transparent to all stakeholders.
- To the extent that CMS wishes to assess costs or savings within the context of competitive bidding, such assessment should take into account all costs, and not just the short-term cost that may be reduced through competitive acquisition. Any assessment of costs or savings should include examination of long-term impact, such as improved patient quality of life, and impact on necessity for follow-up treatment, including hospital inpatient admissions and emergency room and physician office visits, as well as costs to administer the program, that may accrue.

It is only through appropriate guarantees for beneficiary access to innovative technology that competitive bidding will have a chance to successfully address the health care needs of beneficiaries.

An overarching concern we have with the Proposed Rule is that it is a significant expansion beyond the CMS competitive bidding demonstrations. At least for this first round of competitive bidding, we urge CMS to consider only those DMEPOS products that were successfully tested during either of the two Medicare competitive bidding demonstration projects. As you are aware, those two demonstrations were conducted in relatively small geographic areas, and involved considerable "hand holding" by CMS and its contractors, a degree of oversight that is not likely to be possible when competitive bidding is applied simultaneously to ten very large MSAs. As a result, we believe it would be advisable for CMS not to attempt to add product categories early in the life of the new competitive bidding program. This would give the Agency time to assess whether fine tuning is needed in the competitive bidding methodology and related policies (for example, with respect to physician authorization, beneficiary travel and transition issues) before deciding whether the program is ready to be expanded to include additional DMEPOS products.

Should CMS contemplate expansion of products beyond those successfully tested in the demonstrations, AdvaMed would encourage CMS to "test" or phase in a new product or product category in only a single competitive bidding area, and then build on this experience in subsequent rounds of bidding, rather than choosing the far riskier strategy of subjecting such products to competitive bidding in multiple areas from the outset.

There are considerable differences among the range of DMEPOS projects eligible for competitive bidding (for example, with respect to distribution channels, technological sophistication, the role played by manufacturers as opposed to suppliers, the role of ordering physicians, and the impact on beneficiary health and well-being). It would, therefore, be best for CMS to gain real-world experience with each product and product category in a reasonably limited area to minimize risks to beneficiary access, quality of care, and the DMEPOS market itself.

"Education and Outreach"

In the 'Education and Outreach" section, CMS states "[W]e believe that it is important for beneficiaries to learn about the benefits of the Medicare DMEPOS Competitive Bidding Program, such as lower out-of-pocket expenses and increased quality of products from suppliers that have completed the detailed selection process that CMS will require under the program."

This statement assumes that competitive bidding will lead to increased quality, and strongly implies that the suppliers who are successful in competitive bidding will provide higher quality products than suppliers who either choose not to become suppliers or who do not submit winning bids. We do not believe that is necessarily the case, and there is certainly nothing to support that winning bidders will provide higher quality products. We do not believe that it is appropriate for CMS to attempt to 'market' the competitive bidding program as a means to increase quality when there is no evidence to support that this will occur. We also believe that CMS should be very careful regarding any statement that would imply that winning bidders provide better quality items and services. As CMS is aware, suppliers who do not submit winning bids in one MSA can win bids to be suppliers in another MSA. CMS should be aware that overarching and unsupported claims of increased quality can be detrimental to products and suppliers that are not selected for competitive bidding. There will be a myriad of reasons that a particular supplier may not become a supplier in a given MSA -- such as the inability to provide an item in sufficient quantities -- that are completely independent of quality.

"Competitive Bidding Areas"--Proposed § 414.410

The Proposed Rule provides a number of criteria that CMS intends to use to select Metropolitan Statistical Areas (MSAs). However, CMS does not provide any guidance as to which MSAs will be selected. AdvaMed believes it would have been appropriate for CMS to name specific areas to which competitive bidding will be applied. As it currently stands in the Proposed Rule, CMS does not name specific areas, and even proposes expanding competitive bidding outside of MSA boundaries. We do not believe that an expansion of competitive bidding beyond MSA boundaries would be appropriate. CMS made clear in the Proposed Rule that ten of the largest MSAs are scheduled to receive competitive bidding in 2007. Given the enormity of the administrative task of implementing competitive bidding in ten of the largest MSAs, we do not believe it would be feasible to attempt to expand the scope of competitive bidding beyond the boundaries of these areas.

AdvaMed urges CMS to adopt competitive bidding in areas that are somewhat smaller than the MSA to help minimize the risk of a competitive bidding area crossing state lines or areas shared by more than one DMERC. We believe that doing this will make the areas more manageable administratively, and lessen the confusion for suppliers in bidding and for beneficiaries obtaining DMEPOS items.

Additionally, the proposed formula for selecting competitive bidding areas would rely heavily on two measures: (1) DMEPOS allowed charges per beneficiary; and (2) suppliers per beneficiary. We are concerned that neither measure may be completely accurate, which could lead to inequities in the selection of competitive bidding areas.

For example loss or gain of large numbers of beneficiaries during certain portions of the year (the "snowbird" phenomenon) could alter significantly the apparent satisfaction of criteria for selection as a competitive bidding area. DMEPOS allowed charges are credited to the MSA housing a beneficiary's legal residence. If many beneficiaries spend half the year in different MSAs, the estimated demand for DMEPOS in the "legal residence" MSA could be too high and the estimated demand in the "non-legal residence" MSA could be too low. In this case, the number of suppliers in the "legal residence" MSA could appear to be relatively low, while the number of suppliers in the "non-legal residence" MSA could appear to be relatively high. To the extent that Medicare beneficiaries move between identifiable MSAs for extended periods of time, CMS should adjust data on DMEPOS allowed charges and on numbers of beneficiaries and suppliers before selection of competitive bidding areas.

"Nationwide or Regional Mail Order Competitive Bidding Program"—Proposed § 414.410(d)(2)

AdvaMed strongly opposes the proposed provision to implement a national or regional mail order competitive bidding program for DMEPOS equipment and supplies. One of the basic tenets of competitive bidding is to allow the market forces to shape the cost of goods and accessibility to providers and products. Implementing a national or regional mail order DMEPOS competitive biding program—or the proposed mail order alternative requiring Medicare beneficiaries to obtain certain DMEPOS items via mail order suppliers—would manipulate the market rather than promote competition. Mail order suppliers who meet the quality, financial and other Medicare standards are already included under the proposed provisions. There is no need to create a distinct or separate DMEPOS competitive bidding program for mail order.

Additionally, rather than a mandatory requirement for provision of DMEPOS items via mail order, CMS should continue to allow Medicare beneficiaries to obtain their DMEPOS products via their preferred access channel. While some Medicare beneficiaries may choose to obtain certain DMEPOS items via mail order, many Medicare beneficiaries prefer to obtain necessary DMEPOS items from local community suppliers. AdvaMed strongly believes that beneficiary choice must be maintained to ensure that beneficiary adherence to prescribed treatment regimens is not jeopardized.

"Criteria for Item Selection"

CMS proposes to use HCPCS codes individually or grouped together in "product categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the Proposed Rule, we are concerned that use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

We note the importance of very specific, detailed data/information collection and analysis for each product category under consideration for competitive bidding. Every product category has its own unique issues relating to how the products are provided, related services, patient characteristics, distribution channels, and manufacturer's role. Furthermore, such characteristics should be taken into consideration in creating product bundles for bidding. We continue to urge CMS to recognize product-specific variables in all facets of the implementation of the competitive bidding program. In order to ensure that product categories are appropriately defined, we also recommend that CMS seek stakeholder input and publish for comment all proposed product category subdivisions prior to bidding.

We commend CMS for determining that surgical dressings are excluded from competitive bidding due to the lack of savings attributed to these products during two rounds of demonstration projects in Polk County, Florida and San Antonio, Texas. Surgical dressings were did not offer savings through competitive bidding in the demonstrations.

"Establishing Payment Amounts for New DMEPOS Items: 'Gap-Filling"--Proposed § 414.210(g)

Establishing payment amounts for new DMEPOS items is an extremely important process that is unrelated to the <u>implementation</u> of the DMEPOS competitive bidding program. Because of this, AdvaMed believes that it is inappropriate to include this provision within the DMEPOS competitive bidding Proposed Rule and requests that any proposals related to payment for new DMEPOS items be made under a separate rulemaking process. Doing so will ensure that all appropriate stakeholders have an opportunity to properly evaluate and provide comment on the proposed provisions. We also note that CMS is combining coding, coverage, and payment decisions for new DMEPOS technology into a single, newly-created decision-making process. AdvaMed believes that coverage and payment determinations should be separate and distinct processes.

AdvaMed accordingly recommends that CMS deal with the technology assessment issues in a separately published Proposed Rule containing specific procedural

criteria. AdvaMed also recommends that all references to the technology assessment as a part of gap filling be removed from the Final Rule.

"Fee Schedules for Home Dialysis Supplies and Equipment" -- Proposed § 414.107

CMS proposes to implement nationwide fee schedule amounts for home dialysis supplies and equipment currently reimbursed on a reasonable charge basis, effective January 1, 2007. These rates would be based on the average allowed charges for services furnished from January 1, 2005 through December 31, 2005, increased by the percentage change in the Consumer Price Index-Urban (CPI-U) for the 24-month period ending June 2006. In future years, the rates would be updated by the CPI-U for the 12-month period ending in June of the previous year.

AdvaMed agrees that home dialysis reimbursement is an important issue, but does not believe that this issue is related to competitive acquisition of DMEPOS. As such, we recommend that CMS issue a separate Proposed Rule on this payment issue, inviting comments from all stakeholders. This new Proposed Rule should describe how CMS will ensure a smooth transition to the new fee schedule. When CMS introduces a new reimbursement methodology, suppliers are likely to experience additional costs and delayed payment of claims. For example, suppliers of home dialysis supplies and equipment have experienced several changes to the claims process over the past few years. These changes have increased the cost burden of the supplier in the development of line-item claims and in the posting of the reimbursement received. Any further changes should include input from the small number of DME suppliers who currently offer home dialysis supplies and equipment.

CMS notes that it expects the total payments made under the fee schedule will be approximately equal to the total payments that would have been made under the reasonable charge payment methodology. Home dialysis modalities can give patients a better quality of life, allow many patients to remain employed, and can provide considerable savings to the total Medicare program. We ask the Agency to carefully ensure that the fee schedule rates are appropriate to protect beneficiary access to home dialysis treatment.

"The Effect of Competitive Acquisition on Small Suppliers"

AdvaMed believes that competitive acquisition will have a larger negative impact on small suppliers and result in more business consolidation than is currently anticipated by CMS. There are significant variations in DMEPOS suppliers and AdvaMed requests that CMS take into account these differences in its definition of "small" suppliers. Revenue and payer mix are valid measures of supplier "size". However, the types of DMEPOS sold should also be taken into account and separate provisions should be allowed for small suppliers of technologies that require a degree of personal and on-going customer service, such as ostomy supplies. We believe that competitive acquisition may result in negative impacts on beneficiaries that rely on small suppliers.

CMS estimates that 50 percent of bidders will be winners based on the experience with the demonstration projects. Approximately 8,500 small suppliers in the ten competitive bidding areas would lose all Medicare DMEPOS business. We believe that the following are compelling reasons that demonstrate that a much smaller proportion of small suppliers will be successful under the process outlined in the Proposed Rule:

- The methodology used to arrive at a pivotal bid by accumulating capacities in ascending order of bid level is different from what was used in the demonstrations and will likely lead to fewer and larger winners.
- Higher acquisition costs due to new supplier standards and accreditation requirements and the need to bid on every HCPCS code within a product category will inevitably put small suppliers at a disadvantage.
- The contract price will be below the bid price for some successful bidders which introduces a significant financial risk that will be more difficult for smaller suppliers to tolerate.

AdvaMed believes that the Proposed Rule contains inadequate protection for small suppliers. Formation of supplier networks (proposed section 414.418) is an unrealistic option for many small suppliers as this would require a high degree of collaboration with competitors under stressful and unique circumstances, and potentially without knowing the quality standards that they would be required to meet. Small suppliers also may not possess the business resources or experience necessary to form these networks, and will be hard pressed to do so under such short notice. In addition, formation of a network arrangement will likely require costly and lengthy legal arrangements beyond the financial reach of many small suppliers. Lastly, allowing suppliers to bid on only one or a few categories is not a significant benefit to small suppliers because in many cases, they are already specialized and able to bid only a few categories.

To mitigate the impact that competitive acquisition will have on small suppliers, AdvaMed recommends that for small suppliers, CMS relax the rule requiring winning suppliers to cover an entire MSA. While this would impact CMS's determination of supplier capacity and number of winning bids per MSA, it would allow winning small suppliers to service their existing geographic area without the burden of expanding capacity or forming networks. In addition, AdvaMed recommends that the grandfathering provisions in the NPRM be expanded to include all DMEPOS product categories that are subject to competitive bidding and not be limited to rental DME and oxygen supplies. This would allow small suppliers that are willing to accept the contract prices for their MSA and meet the accreditation and quality standards, the opportunity to continue servicing their existing Medicare customers and potentially stay in business until the next bid period. Finally, AdvaMed recommends that if CMS decides to allow mail order suppliers to participate in DMEPOS competitive bidding prior to 2010, those mail order suppliers should not count towards the two-supplier minimum that CMS is establishing in each competitive bidding area.

"DMEPOS Manufacturers as Suppliers"-- Proposed §414.412

The Proposed Rule does not propose specific product categories, but it does list policy groups and assumes that interested bidders would be required to submit bids on all items included in a product category. However, in the case of DMEPOS products for which manufacturers now serve as suppliers, the requirement to bid on all HCPCS codes in a product category could be a major problem, especially if the product categories are very broad. In fact, this policy could impact beneficiary access and significantly disrupt the existing marketplace for some DMEPOS products.

CMS could simply exclude from competitive bidding those DMEPOS products now commonly provided directly by manufacturers, perhaps on the grounds that these products are available from relatively few suppliers and would not produce Medicare savings. Alternatively, the Agency could also adopt special rules for manufacturers wishing to bid, permitting them to bid only on the products they manufacture. If CMS chooses this last option, it would also need to modify its proposed method for calculating composite bids and selecting contract suppliers. In sum, we wish to highlight the fact that CMS could inadvertently end up precluding manufacturers from continuing to serve as suppliers in competitive bidding areas to the detriment of the Medicare beneficiaries living in these locales.

"Physician Authorization/Treating Practitioner"--Proposed §414.420

The Proposed Rule would keep intact the provision that permits a physician to prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome (section §414.440). However, the Proposed Rule defines physicians as doctors of medicine or osteopathy in accordance with section 1861(r)(1)) of the Social Security Act), a definition that excludes dentists, podiatrists, and optometrists, who may order DMEPOS. At the same time, the Proposed Rule would expand the provision by allowing certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists to order a particular brand or mode of delivery. AdvaMed recommends that CMS expand the definition of physician to allow podiatrists, optometrists, and dentists to prescribe a particular brand or mode of delivery of DMEPOS, along with physician assistants, nurse practitioners, and clinical nurse specialists.

As CMS correctly notes in the Proposed Rule, suppliers under competitive bidding may only offer certain brands within a HCPCS code. AdvaMed supports CMS's decision to permit a variety of qualified practitioners, in addition to physicians, to prescribe particular brands or modes of delivery where appropriate. We believe this will help to ensure that patients have access to the most appropriate treatments and technologies, leading to enhanced quality of care. While the expansion of this provision is highly positive, AdvaMed urges CMS to build in sufficient flexibility so that the physician authorization process will rarely be used.

When there is a need for a physician authorization, AdvaMed urges CMS to:

- 1) Implement a simple authorization process, especially in the early rounds of the competitive bidding program. While the standard suggested by CMS in the Proposed Rule would allow a qualified practitioner to prescribe specifically to avoid an adverse outcome, we believe that CMS should recognize that certain products, such as blood glucose monitors, may not fit neatly within what may traditionally have been considered in the context of avoiding an adverse outcome. However, there are multiple features in the many blood glucose monitoring systems currently available such that a physician may specify a particular brand to meet the beneficiary's needs at that time. A prescription for the most appropriate product can be determinative regarding whether a patient will follow a treatment regimen; and
- 2) Keep this authorization process very simple. For example, having the physician or other practitioner document in the patient's record and on the prescription form the specific product brand or mode of delivery required for the beneficiary. CMS has a similar documentation policy for beneficiaries receiving additional glucose test strips per month. This process helps to ensure that the right products are received by the beneficiary based on the qualified provider's decision, and also allows CMS, if necessary, to review the reason for the use of the particular product or supply.

"Skilled Nursing Providers"--Proposed §414.404, §414.422

AdvaMed believes that beneficiaries in skilled nursing and long-term care facilities are substantially different from much of the Medicare home care populations, and that including Skilled Nursing Facilities (SNFs) and Long-Term Care Facilities (LTCFs) patients/residents within the competitive bidding process that is essentially designed for home care patients will potentially create problems that should be addressed by CMS. We refer here to the 'long-term care facilities' that serve dually eligible beneficiaries, with Medicare paying for Part B covered services and Medicaid covering custodial care. We ask that CMS consider the following:

- O The Proposed Rule permits a SNF/LTCF to submit a bid to care for their own patients/residents. SNF/LTCF patients are more dependent, frail, and vulnerable than patients cared for at home. More than 80 percent of all enteral patients residing in SNFs/ LTCFs, for example, require an enteral pump for safe delivery of nutrition, while less than half of all enteral patients residing in their homes have such a requirement. The difference in the severity of illness of patients in these two care settings should be recognized in the bid process.
- o The proposed quality standards are explicitly designed to govern home care. Care provided in SNFs and LTCFs is covered by existing facility care standards. The proposed standards are unclear about the application of product-specific standards in situations where products are provided by a

supplier that shares responsibility for patient care with a SNF, LTCF or a home health agency. Quality standards need to be explicit about supplier patient care responsibility in these shared-responsibility situations.

o If a SNF or LTCF is unsuccessful in winning a contract, the facility will be required to recruit an outside supplier to provide inpatient care. The outside supplier would be unfamiliar with the facility's operational procedures and patient care requirements. In some situations, the transition could replace an effective internal patient care system with an unknown guest firm. We are concerned that this could cause disruption to quality, as various providers would be responsible for different facets of the supplies provided to patients, resulting in fragmented accountability for quality and greater difficulty in the ability to coordinate the receipt of supplies with overall residents' needs.

AdvaMed recommends that CMS consider modifying the Proposed Rule to exclude patients that are in institutional settings, or, alternatively, exempt DMEPOS products that are primarily used in SNFs/LTCFs pending further examination. We believe that these issues need further examination, including potentially a separate set of quality standards for SNF/LTCF suppliers, published through notice and comment rulemaking, to ensure quality DMEPOS for SNF/LTCF residents should the SNF/LTCF not be the supplier under a competitive bidding arrangement. Postponement of applicability of this Proposed Rule to institutionalized patients would allow CMS to conduct the kind of in-depth analysis and examination that is necessary to address these issues. We recommend that CMS consider the ongoing difficulties SNFs and LTCFs are currently experiencing with the transition of their residents to the new Medicare Part D drug benefit. We recommend that CMS postpone DMEPOS competitive bidding in these settings until CMS can convene a working group of key stakeholders to examine the requirements for a competitive bidding program in these facilities.

"Determining Single Payment Amounts for Individual Items"-- Proposed 414.416(b)

The Proposed Rule shifts the calculation of the single payment rate from the pivotal bid (the highest winning composite bid, the price that all bidders have accepted) to the median of all winning bids. This change in the calculation methodology will decrease provider payment rates dramatically. AdvaMed believes that the use of a median statistic is flawed for the following reasons:

- o The demonstration projects employed an Adjustment Factor Method (AFM), evidently without confusion or obstacle. The Medicare Modernization Act provision expanding competitive bidding was based on the AFM's proven methodology.
- o Calculations of an unweighted median could be vulnerable to a variety of gaming strategies, as providers serving a few Part B beneficiaries have the same impact on the calculation of the median value as providers responsible

for a large number of beneficiaries. Bidders with a small percentage of their total business through Part B could submit low bids, driving down the median rates. If CMS insists on using a median rate, bids should be weighted by proposed capacity, so payment rates will more accurately represent the market of successful bidders.

AdvaMed requests that the median of supplier bids not be used by CMS, but that CMS instead use the same "Adjustment Factor Method" used in the competitive bidding demonstrations. Given that the scope of the Proposed Rule is significantly greater than that of the demonstrations, we do not believe now is the appropriate time for CMS to deviate from the statistical basis that was used in the demonstrations to determine successful bids.

Also, we believe quite strongly that only the bids of fully accredited suppliers should be used to determine the single payment amounts under the DMEPOS competitive bidding program. From the information available to us, we presume that CMS agrees. If so, then the Agency should take steps to assure that any bids submitted prior to accreditation are not used in payment calculations unless the submitting bidder has subsequently been accredited. Otherwise, there is simply too great a risk that the bids of unaccredited suppliers could bias the payment calculation.

"Review of Financial Standards"--Proposed 414.414(d)

Financial standards are a significant component in the approval process for candidate bidders. The authorizing legislation states that the Secretary may not award a contract to an entity that does not meet applicable financial standards. The Proposed Rule invites comments on financial standards, while describing the documents that might be required from bidders. Proposing data collection instruments is not the same as proposing financial eligibility standards. CMS should first consider the difficult question of which financial standards are appropriate, then determine the documentation needed to implement those standards.

The establishment of financial standards for Part B providers is an unprecedented task. While financial standards exist for managed care organizations, hospitals and other cost reporting providers, such standards will not easily or automatically translate to the diverse DMEPOS markets. These financial standards must be flexible enough to regulate mail order companies, small local DME dealers, skilled nursing facilities, departments of hospitals, retail pharmacies, publicly-traded national corporations and privately-held family firms.

Development of these standards will require careful thought and insightful help from well-informed consultants. We encourage CMS to assign a priority to this program linchpin, and to bring this issue to the PAOC at the next available meeting. Given the obligation of the PAOC to advise the Secretary on an issue which can, by itself, determine whether a company continues within Medicare or not, this important issue needs full and candid examination. The opportunities for serious inadvertent errors

should not be underestimated. If financial standards are too restrictive, then qualified suppliers and new companies without a financial history will be eliminated from the Medicare Part B program. On the other hand, if financial standards are too lax, then suppliers may be unable to meet the challenges of a competitive acquisition market with potentially dramatic implications for patients under their care.

"Payment Basis"--Proposed §414.408

The Proposed Rule describes a potential grandfathering process for certain rental agreements. However, we believe that a comprehensive transition policy will be essential to a successful roll-out of the new DMEPOS competitive bidding program.

- We urge CMS to allow beneficiaries in a new competitive bidding area to continue to obtain DMEPOS products that are subject to competitive bidding from non-contract suppliers during a transition period.
- We also recommend that, for DMEPOS products that require regular replacement supplies, CMS assure that Medicare beneficiaries can continue to obtain needed replacement supplies for their current equipment through careful consideration of options for transitioning to suppliers under competitive bidding.

For beneficiaries in a new competitive bidding area, we propose that non-contract suppliers could continue to be paid at the established fee schedule amounts. We propose this would occur over a relatively short period of time, during which beneficiary educational materials would be made available to non-contract suppliers for distribution to beneficiaries at the time of a DMEPOS transaction. The materials would explain the new competitive bidding program, list the DMEPOS products subject to competitive bidding in the area, identify the contract suppliers selected by CMS, and provide other important information, such as contact information for Medicare contractors, ombudsmen, and CMS personnel.

For DMEPOS products that require regular replacement supplies, CMS could simply require contract suppliers to provide the replacement supplies in question during a transition period even if they did not plan to offer that specific brand of replacement supplies for the full contract period.

The Proposed Rule addresses various beneficiary travel scenarios. AdvaMed believes that CMS should ensure that beneficiaries who may travel outside their competitive bidding area (CBA) would be able to obtain their DMEPOS items. For example, a beneficiary could lose or damage her blood glucose test strips and need to purchase replacement test strips that day. It is not realistic for a beneficiary whose residence is in a particular CBA to know what DMEPOS items are being competitively bid in a different CBA that the beneficiary may be visiting for medical or personal reasons, locate contracted suppliers in that area, and identify what contracted supplier has the brand of DMEPOS they are using. In fact, it is a distinct possibility that none of the contract suppliers in the area that

a beneficiary may be visiting would be offering the specific brand of replacement supplies that the beneficiary needs for their current brand of DMEPOS product. We therefore urge CMS to take all of these practical considerations into account in adopting a reasonable travel policy that would ensure beneficiary access to replacement supplies during travel.

AdvaMed accordingly recommends CMS take these practical considerations into account and adopt a reasonable travel policy that would ensure beneficiary access to supplies, including replacement supplies, during times when beneficiaries travel outside of their CBA. AdvaMed supports allowing beneficiaries to purchase their DMEPOS products (especially replacement supplies) from any community Medicare supplier who is either a Medicare participating supplier or a nonparticipating supplier who will agree to accept assignment for the DMEPOS equipment and supplies.

While we can understand CMS's desire to start a new competitive bidding program on a date certain with no transition, we believe that there could be considerable confusion and beneficiary dissatisfaction if some type of short-term transition period is not adopted. The transition period that we recommend CMS consider would give beneficiaries time to consult with their doctor or other health professional about the appropriateness of switching to one of the brands of DMEPOS available under competitive bidding or, if need be, execute a physician authorization to assure continued access to their current brand if required to prevent an adverse medical outcome.

"Conditions for Awarding Contracts"--Proposed §414.414

CMS expects bidding suppliers to meet its quality standards and be accredited by a CMS-approved organization. However, the Proposed Rule notes that a grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. The length of this grace period (which would be specified in the request for bid) would be determined "by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area." The Proposed Rule also notes that suppliers that received "a valid accreditation before CMS-approved accreditation organizations are designated" will be considered to be grandfathered if the accreditation was granted by an organization that CMS ultimately designates.

We are concerned that CMS is making unrealistic assumptions about how quickly the accreditation process can be implemented and assess large numbers of suppliers, even if the immediate focus is only on suppliers in ten large MSAs. As we understand it, CMS plans to issue a solicitation for accrediting bodies only after publication of a final rule. The selection of accrediting bodies itself would presumably take a fair amount of time. Selected organizations would also likely require time to gear up, hire additional staff, adopt new policies and procedures and otherwise prepare to take on the new workload. We urge CMS to pay very careful attention to the timeline and not attempt to rush the accreditation process. Moreover, as we emphasize elsewhere in these comments, it would be completely inappropriate to use bids submitted by suppliers that have not been

accredited in calculating the single payment amounts. It would also be inappropriate to consider such bids in determining the pivotal bid or in selecting contract suppliers.

In the Proposed Rule, CMS clearly indicates that it wishes to match supply and demand in selecting the number of winning suppliers. However, the geographic distribution of winning suppliers is never mentioned, and there is no indication in the Proposed Rule that CMS was planning to take this into account. While the geographic distribution of contract suppliers will be important for all DMEPOS, it will be especially important for products typically obtained by the beneficiary through local type of outlets, such as a nearby pharmacy or other retail outlet. Of course, assuring a reasonable geographic distribution of contract suppliers will not be easy and will require an in-depth understanding of each competitive bidding area (for example, natural boundaries, road conditions, travel times, the availability of public transportation, and the distribution of beneficiaries across the area). However, if competitive bidding produces a serious mismatch between the location of contract suppliers and the location of Medicare beneficiaries, certain segments of the beneficiary population could be seriously disadvantaged.

Given this risk, we believe that the bid-evaluation process should incorporate a mechanism for assuring beneficiary access throughout the. The determination of supplier capacity should assure that all residents within an MSA can receive products from successful bidders. After an initial determination of capacity, CMS could analyze capacity by zip code, to assure that patients within each zip code would be served by several winning bidders. Appropriate adjustments to the list of winning suppliers may need to be implemented if convenient access is lacking. Policies regarding these adjustments and disclosure of these decisions should be announced in the Final Rule.

Congress addressed the issue of geographic distribution in the context of Medicare Part D by specifying that each prescription drug plan must have a network of pharmacies that ensures "convenient access." TRICARE standards are being used as a model for assessing the network. Specifically, under the Part D program, drug plans must establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

We believe that Medicare's DMEPOS competitive bidding program should provide a similar level of "convenient access" for DMEPOS products, especially those typically obtained by beneficiaries from retail outlets, such as a local pharmacy. The Final Rule needs to discuss the issue of geographic distribution of contract suppliers and indicate how CMS plans to address it.

"Assurance of Savings" -- Proposed §414.414(f)

To assure savings from competitive bidding, CMS proposes to require that single payment amounts for <u>each item</u> in a product category may not exceed the current fee schedule amount for that item. Furthermore, CMS proposes not to accept any bid for an item that is higher than the current fee schedule amount for that item.

AdvaMed believes that limiting bids for all items in a product category is overly restrictive, and could lessen savings from competitive bidding. Instead, CMS should permit potential suppliers to bid based on their costs of providing each item. For some items, costs could be lower than the fee schedule amount, while for other items, costs could be higher.

AdvaMed supports the alternative CMS interpretation of "less than the total amounts that would otherwise be paid" which is based on <u>product category</u> instead of each item within the category. CMS could still meet its requirement—to award contracts only if savings are anticipated—by accepting bids where payment amounts for the product <u>category</u> are below fee schedule amounts for items in that product category. If CMS requires bids for all items to be below fee schedule amounts, and suppliers can provide only some items below the fee schedule amount, the suppliers will be: 1) prohibited from participating; or 2) forced to cross-subsidize within the product category.

In the Proposed Rule, CMS notes that during the demonstrations, several product categories received overall savings but payment amounts increased for a few individual items within those product categories. CMS notes that "this may not result in adequate savings." We disagree with this conclusion from the demonstrations. Instead, we would argue that these results indicate inaccuracies in the fee schedule amount for both items with competitive bids below the fee schedule amount (which would produce savings to Medicare) and items with competitive bids above the fee schedule amount (which would produce costs to the program). The goal of a competitive bidding program should be to assure that Medicare payments align with the costs of providing high quality services, while continuing to encourage access to advances in medical technologies.

"Fee Schedule Updates for Class III Devices"

The background section of the Proposed Rule requests solicitation of comments on the appropriate Medicare fee schedule percentage change for Class III durable medical equipment for 2007 and 2008. CMS noted that they will consider these comments in conjunction with recommendations made in a March 2006 Government Accountability Office (GAO) report. The Food and Drug Administration (FDA) regulation at 21 C.F.R. section 860.3(c)(3), notes that Class III devices usually support or sustain life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Under the DME fee schedule, Class III devices

include osteogenesis stimulators, infusion pumps and their related supplies, neuromuscular stimulators, certain ultraviolet light therapy systems, and automatic external defibrillators and related supplies.

In the Proposed Rule, CMS alludes to recommendations made by the GAO in a March 2006 report. In that report, GAO recommended that the Secretary of Health and Human Services establish "a uniform payment update" for 2007 for both Class II and Class III devices, and that the Congress consider establishing such a uniform update for 2008. AdvaMed finds this GAO report disappointing. Instead of providing a full assessment of changes over time in the costs of producing, supplying and servicing Class III devices, the GAO report focuses only on selected issues, mainly pre-marketing costs. Further, in saying that the updates for Class II and Class III devices should be "uniform" or "the same," the GAO report never actually specifies what the specific percentage update for 2007 or 2008 should be. The GAO report does assert that Class III devices do not warrant a distinct annual payment update. However, in addition to its shortcoming with regard to a lack of a specific payment update, the report fails to include a rigorous assessment of payment adequacy, and does not review the many factors contributing to manufacturer costs and changes in these costs over time. In addition, the report examines Class III devices in relation to only a very limited number of higher-technology Class II items that may not be reflective of Class II items more generally. The report acknowledges that an earlier draft was criticized for failing to recommend a specific percentage update.

We recognize that the Medicare Modernization Act specified that the update for Class II devices for 2007 and 2008 should be zero, but we note that the GAO report never explicitly says that its analysis supports a zero update for Class III—or even Class II—devices. Given changes in prices in the economy at large, we believe it would be unreasonable to assume that Class III device manufacturers and suppliers are somehow immune from the cost pressures being felt elsewhere in the economy.

We recommend that CMS continue using the CPI-U to adjust Medicare fee schedule amounts for Class III devices. We note that CMS stated that the Agency will use this same adjustment factor to update the single payment amounts in years 2 and 3 of a DMEPOS competitive bidding cycle. We presume this means that CMS considers CPI-U to be a reasonable estimate of changes in supplier costs over time. Of course, under DMEPOS competitive bidding, these changes in supplier costs would relate to Class II devices, and not the more sophisticated Class III devices, which Congress chose to exclude from the new competitive bidding program.

"Rebate Program" - (Proposed 414.416(c))

CMS proposes to allow contract suppliers to provide beneficiaries with rebates. The rebate would occur in instances when the supplier submitted bids for an individual item in an amount below the single payment amount. The rebate would be equal to the difference between the provider's actual bid and the single payment amount.

The Proposed Rule suggests that rebates would be voluntary but that contract suppliers would not be able to implement them on a case-by-case basis. If a contract supplier submits a bid below the single payment amount and chooses to offer a rebate, the supplier would have to offer the rebate to all Medicare beneficiaries receiving the competitively bid item to which the rebate applies. According to CMS, if a supplier chooses to provide a rebate, the rebate would become a binding contractual commitment for that particular supplier to all beneficiaries receiving the item from that supplier. Once agreed to, contract suppliers would be prohibited from altering the provision of a rebate during the term of the contract. Contract suppliers would be prohibited from "directly or indirectly" advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals. However, this would not preclude CMS from providing to beneficiaries comparative information about contract suppliers that offer rebates. Only contract suppliers that submitted bids below the single payment amount would be allowed to issue rebates. CMS believes that allowing suppliers to offer rebates will give beneficiaries the ability to realize additional savings and the full benefits of the Medicare DEMPOS Competitive Bidding Program.

AdvaMed does not believe that the rebate provision should be included in competitive bidding. Such payments could be considered inducements to beneficiaries and potentially violate the Federal Anti-Kickback Statute (Statute). It is fairly certain that rebates provided directly to beneficiaries would fall under the Statute's purview as a form of inducement to beneficiaries in exchange for referrals. The Statute prohibits the knowing and willful offering or giving of remuneration either in return for referrals or with the intent to induce referrals for items and services reimbursed by Medicare.

In order to ensure that they would not run afoul of the Statute's prohibitions, suppliers would thus have to ensure that their provision of discounts would fall within one of the safe harbor provisions, such as the discount safe harbor. This is an additional layer of legal complexity that is being added in an ad hoc fashion to competitive bidding, in addition to an already large number of potential changes. AdvaMed believes that it would be difficult for suppliers to provide any form of rebate without assuming the uncertainty of additional risk under the Statute.

The rebate proposal also creates a tension with the Federal Anti-Kickback Statute's safe harbor for discount arrangements. To qualify for the discount safe harbor, a rebate must be disclosed in writing to the buyer at the time of the initial purchase to which the discount applies. However, the Proposed Rule contains an express prohibition on the supplier from advertising either directly or indirectly to beneficiaries, referral sources, or prescribing health care professionals. It is difficult to envision a sufficient window of time during which suppliers could meet both the discount safe harbor (requiring disclosure in advance of the arrangement) and the regulation's prohibition on advertising of the rebate (which would appear to apply to the supplier informing the beneficiary directly about the rebate after it is official).

It thus appears unlikely that a supplier could offer a rebate and gain the safe harbor's protections. At a minimum, these limitations greatly limit the circumstances under which

suppliers can be assured of protections against prosecution under the Statute. At a maximum, there could be no way to meet the regulatory requirements and the safe harbor criteria. If CMS provides for rebates in the Final Rule, AdvaMed believes that CMS should address this issue completely and provide very clear details before implementing any rebate provision in competitive bidding.

AdvaMed believes that it would be inappropriate for suppliers to be exposed as potential test cases for the limits of this regulatory authority. AdvaMed believes it would be appropriate to offer a safe harbor to suppliers to enable full disclosure of discounts to beneficiaries pursuant to competitive bidding. AdvaMed also questions whether CMS should take the position that rebates, once offered, should become a 'binding contractual commitment' when an express contractual provision would not exist. AdvaMed also believes that CMS's implementation of competitive bidding should allow suppliers to supply products at the standard payment amount, and not at arbitrary prices that would vary based upon supplier willingness to offer rebates after the fact. Allowing a supplier to provide a rebate would create such a discrepancy. Additionally, while CMS believes that this could potentially drive down prices, there is no evidence that this would occur. Any enhancement of future price-cutting based on offering a rebate is uncertain. What is more certain is that confusion will likely be caused by some suppliers offering rebates and others not doing so, and difficulty beneficiaries will have keeping fully apprised regarding which suppliers are offering rebates. The problems will be aggravated by situations in which beneficiaries are traveling outside of their home MSA. AdvaMed does not believe it would be appropriate for CMS to be permitted to disclose these rebates when the regulation would prohibit suppliers from doing so. Absent explicit safe harbor protections and complete reworking of the advertising prohibition, AdvaMed does not believe rebates should be included in competitive bidding.

CONCLUSION

The Proposed Rule provides a framework for competitive bidding but leaves unanswered many critical questions and issues. We have highlighted a number of these in our letter. Our central points are: 1) the Proposed Rule lacks both parameters and an important degree of specificity that we view as absolutely critical to allowing manufacturers and suppliers to participate fully, conform to the program's structure, and provide the highest quality DMEPOS items and services to Medicare beneficiaries; 2) the Proposed Rule contains several items, such as a technology assessment and commentary on the pricing of Class III devices, that are unrelated to competitive bidding and should not be included in the Proposed or Final Rules; 3) the Proposed Rule is simply too encompassing and potentially too problematic to administer, and leaves many parameters of such central importance unspecified in the Proposed Rule which would have to be addressed before the start of the program; and 4) to the extent that CMS wishes to assess costs within the context of competitive bidding, such assessment should take into account all costs, including long-term cost impact, improved quality of life, costs to administer the program and impact on necessity for follow-up treatment.

We welcome the opportunity to work with CMS on these issues to ensure that beneficiaries continue to receive appropriate care and full benefit from advances in medical technology.

Sincerely,

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Comments on Medicare Competitive Bidding draft proposal CMS file code CMS-1270-P

Submitted by: Patrick Naeger

Rebates (§414.416(c))

This is a notion that took everyone by surprise and with good reason. It appears contrary to decades of healthcare law and rules that prohibit Medicare providers from offering beneficiaries rebates on healthcare items and services (remember the beneficiary inducement statute?). The rebate concept is structured to encourage providers to submit the lowest bid possible—so they can increase their chances of winning the bid and gain an advantage over other winning providers. The greater the difference between the provider's low bid and the winning bid amount, the greater the cash rebate the beneficiary will be able to pocket if he chooses you. For the consumer, that's a pretty attractive proposition. Think about it: When the rebate amount is greater than the beneficiary's co-payment amount, you could be paying patients to use your services! In an attempt to address the obvious legal issues, CMS proposes that providers not be able to advertise rebates. Presumably, the government will advertise the respective rebates of various winning providers. Interesting. This section is extremely flawed and should be reconsidered.

Grandfathering (§414.408)

If a provider loses the bid and no longer wishes to serve his existing Medicare beneficiaries, winning HMEs must take over that business. That means winners will have to provide ongoing rentals for beneficiaries with medical needs for cap rental items or oxygen. For example, a winning provider may be required to take on 100 hospital bed rentals that have been occurring for 11 months or oxygen rentals that have been occurring for 30 months. As CMS states in the proposed rule, providers should be accounting for these additional costs when determining the bid to submit for particular items. While CMS will have estimated projected utilization for each HCPCS code it intends to bid, CMS will not be able to provide information regarding how many beneficiaries have been renting a hospital bed or have been on home oxygen therapy by the time the contract will begin. How then can any provider begin to intelligently calculate these additional costs into their bids? This becomes a huge liability to the providers where as in many cases by inheriting the Medicare beneficiary at a debt and the provider suffers significant losses in this types of scenario.

Quality Standards (§414.414)

One of the largest and yet to be resolved issues is the Quality Standards. While the proposed rule was officially published May 1, and CMS scheduled a meeting of the Program Advisory and Oversight Committee (PAOC) in late May, the final Quality Standards were not scheduled to be issued until sometime in June. Quality Standards are so integral to the implementation of competitive bidding that it is difficult to provide meaningful comments to the proposed rule while we are unaware of the content and requirements of the Quality Standards. Perhaps the one positive statement in the entire competitive bidding proposed rule is CMS's apparent attempt to make sure that Quality Standards are implemented at the same time as competitive bidding, and that providers in the initial bid geographic areas will be required to be accredited by an organization whose standards are determined by CMS to meet the CMS Quality Standards. But at another point in the proposed rule, CMS states that the accreditation organizations will be able to grant providers in a bid area a grace period to become accredited within some unstated period of time. Now that's clarity.

Getting It Right Is More Important than Rushing Implementation

CMS should stagger the bidding in MSAs in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Also, the initial MSAs and products selected should be identified in the final rule. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

Have Accreditation and Standards in Place before Starting

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies *now*. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

Make Competitive Bidding Competitive, and Sustainable

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. This portion of the rule is predicated on the illusion that some how the current fee schedules are adequate to sustain providers. In fact there are provisions in the rule that essentially require the provider to provide equipment to

a patient that is brand specific if the physician so orders. If the CB providers bid was based on a relationship they have with a manufacturer for a specific brand then there will be a substantial burden on the provider to bear the cost of a specific brand. This will adversely impact the provider.

What is CMS proposing if a doctor writes a prescription for a brand name product that. a provider is contractually unable to provide:

Examples:

- A. A physician writes a prescription for a Hoverround power wheelchair. Hoverround is a manufacturer that follows a direct to consumer business model. The winning provider will not be able to supply a Hoverround product because Hoverround will not sell the product to the winning provider. What will be CMS's solution to this problem?
- B. A physician writes a prescription for a portable concentrator. The manufacturer of the portable concentrator has a distribution contract with a non winning provider. In this case the winning provider will not be able to provide that equipment due to the contract. What will be CMS's solution to this problem?

If the physician writes a prescription for a product that the acquisition cost for the product is below the reimbursement for the product - what options does the provider have to substitute for the brand name?

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Impact Analysis

In this section, a number of statements appear to directly contradict other statements in this section and throughout the rule, particularly regarding the ability of smaller providers to successfully bid in the programs. While CMS continually alludes to the demonstration programs in Polk County and San Antonio, stating that small providers were able to successfully participate in those bids, CMS's impact statement says that this rule "will have a significant impact on a substantial number of small providers." Two pages later, CMS continues: "We

anticipate that the bidding process will be designed to neither reward nor penalize small providers." In a similar vein, CMS states that "since providers can choose whether to submit a bid for the competitive bid program, the regulation imposes no direct cost." Sure, if you don't submit a bid you don't incur the costs of submitting a bid; but if you don't submit a bid you have eliminated all chances for becoming a winning provider. Furthermore CMS proposes to put into place a whole new bureaucracy in order to formulate, analyze and evaluate all the bids. What additional cost will this mean. Will there be any savings after that bill is paid?

CMS has published that they are expecting competitive bidding to provide a 20% cost savings based on the demonstration projects and that CMS feels that 20% cost savings is achievable. In this projection CMS has failed to consider the following:

A. Increase operational costs that have occurred since 2002:

- 1. Gas
- 2. Insurance-Liability, Auto, workers compensation, and Health insurance
- 3. Personnel costs- Raises
- 4. 2003 and 2004 CPI freezes
- 5. The FEBHP allowable cuts that occurred Jan 1, 2005
- 6. The general and administrative costs to administer the program

With the above mentioned increases and cuts, how is CMS calculating a 20% cost savings? We would like to see the projected cost savings example to verify the accuracy of CMS's prediction. CMS should be more concerned about providing an accurate savings prediction rather than a politically sensitive savings prediction.

Bullet Point Comments Regarding MSA Selection Criteria Background Information

Section 1847(a)(3) of the Act allows CMS to exempt from the Medicare DMEPOS Competitive Bidding Program rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item. CMS proposes to use this authority to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or
- Low number of Medicare FFS beneficiaries in the area relative to other similar geographic areas.

CMS proposes to make decisions regarding what constitutes low (non-competitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, CMS proposes to use the definitions currently in §412.64(b)(1)(ii) of the regulations. CMS invites comments on the methodologies proposed for determining whether an area within an urban area that has a low population density is not competitive. CMS will be reviewing the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, CMS also invites comments on standards for exempting particular rural areas from competitive bidding.

Comments:

- 1. Rural areas tend to be underserved under the present system. Providers routinely travel hundreds of miles to provide services in various areas of the country. Travel costs have never been covered by Medicare.
- 2. In certain areas of the country complex Rehab Technology services are available from only one or two providers for several hundred miles in any direction. Access is already compromised in many areas as a result.
- 3. CMS has no published criteria outlining the optimal number of providers serving a geographic area. Furthermore there is nothing to indicate once the winners are picked what time frame would be used to establish whether or not there are adequate providers to serve the CB area. The greatest fallacy in this is that once some of these suppliers are not the successful bidder it won't be long and they will be out of business. Then who would be called on to fill the void. There are no network adequacies standards what-so-ever for CMS to follow.
- 4. The proposed criteria to use a review of the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding is subjective at best.
- 5. The analysis of the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas may not reflect reality. This is due to the great distance that patients must travel to receive services in rural areas of the country. In addition discrimination is a problematic area, especially in remote areas with significant lower income populations where beneficiaries already have limited access to services due to significant transportation issues. Rural areas tend to have a greater percentage of elderly population compared to urban areas, and these areas already suffer from a primary care physician shortage.

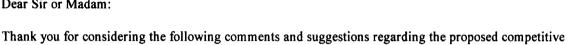


June 16, 2006

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:



Competitive Bidding Areas

bidding program for DMEPOS.

- We strongly oppose CMS' proposal that would eliminate beneficiaries freedom to choose where to obtain their replacement supplies of certain DMEPOS. Beneficiaries access to DMEPOS will be severely restricted which may lead to a decline in patient compliance and positive therapeutic
- Exceptions must be made for those suppliers who provide DMEPOS to beneficiaries that reside in rural communities. Competitive bidding areas should exclude rural suppliers even if to some the commute may seem feasible. Many beneficiaries will not have access or transportation in order to obtain DMEPOS from a selected competitive bidding area outside of their rural community.
- Therapeutic relationships may be hindered if beneficiaries are required to obtain DMEPOS supplies from a designated supplier. Small suppliers have the ability to build therapeutic relationships with their beneficiaries due to the smaller market. Positive therapeutic outcomes rely on beneficiaries receiving their medications, DMEPOS, and education from the same supplier.

Criteria for Item Selection

- The competitive bidding program should not include DMEPOS supplies that require convenient and frequent access such as diabetic testing supplies. Managing patients with diabetes requires frequent changes in therapy and testing supplies need to be easily accessible whenever changes are necessary.
- The competitive bidding program should also exclude items such as walkers, canes, and respiratory medications. Beneficiaries often need these items immediately. Obtaining these supplies may be delayed for many beneficiaries due to the need to travel to a designated area.

Opportunity for Participation by Small Suppliers

- Small suppliers in rural communities should be allowed a separate competitive bidding area or be exempt from the proposal. Rural suppliers are unique in that they provide services and DMEPOS supplies to a small market. It is imperative that small suppliers are able to continue to provide these services/supplies for their beneficiaries. Many rural suppliers would not be able to compete with larger suppliers in metropolitan areas. Small suppliers that offer a lower bid in order to be contracted will likely lose money on every sale due to the proposal of the single payment for each item
- We currently provide the following types of DMEPOS in our practice: diabetic testing supplies, walkers, canes, orthotics, and respiratory medications. If revisions are not made to the final regulation we will not be able to provide these services to members of our rural community.
- In conclusion, We urge CMS to revise the regulation to allow beneficiaries to continue to choose where to obtain their DMEPOS supplies. Especially for beneficiaries in rural communities where commuting to obtain DMEPOS is not convenient or possible. Small rural suppliers must be given special consideration in order to continue providing DMEPOS supplies for beneficiaries in rural communities. Certain supplies such as diabetic testing supplies, walkers, canes, orthotics, and



respiratory medications should not be included in the competitive bidding program due to the need for convenient and frequent access.

Thank you for considering our views and concerns.

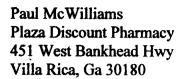
Sincerely,

Melrose Pharmacy Inc.

Stacy Meyer

Jeff Sawyer

6/19/06





To Whom It May Concern:

After reading the recent proposals for certain segments of the DME program I am extremely upset that a mandatory mail order would even be considered. Taking away the patients ability to have personal contact with the provider is a huge mistake. Patients should have the ability to choose a provider and most will not choose mail order unless they are coerced. In the past I have had patients switch to us from the mail order services seen on television. Many times they had been sent supplies without requesting them and in some instances had large stockpiles of products. Patients only receive supplies when requested from our Pharmacy.

I am willing to accept a competitive bidding process as long as the small supplier is not left out. Our health care system needs some reform but destroying the ability of local DME providers to stay in business is not a good idea. Our pharmacy is a one stop shop for patients who want medications and supplies or equipment. Many times people need help immediately and want to deal with someone they trust and know.

Our nation's pharmacies have had to shoulder the burden of Medicare part D. Many had to borrow money just to make up for delayed payments. Now for those of us who supply DME items we are potentially being dealt another blow. Mandatory mail order and blocking small legitimate suppliers is not the way to save money in the long term. It certainly is not the way to take care of patients either.

Sincerely.

Paul McWilliams, R.Ph

JoAnn Shropshire, OTR/CHT
Karen L. Sipp, OTR/CHT
Connie L.S. Simon, OTR/CHT
Holly W. Renard, OTR/CHT
Laurie Petrie-Kampa, OTR/CHT
Nicole A. Salm, OTR/CHT
Maureen McGrath-Doran, OTR/CHT
Ann Porretto-Loehrke, PT/CHT/COMT
Julie A. Ver Straate, OTR/CHT



Anne M.E. Harrmann, OTR
Teresa O'Hearn, PT/DPT
Troy Gutzman, OTR/CHT/CEES
Elizabeth Soika, MSPT
Christine Jesko, OTR
Sofija Seymour, MPT/CHT
Laurie Field, OTR/CHT
Donna Nennig, OTR
J. Michelle Mueller, PT

June 19, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan.

I am writing to express my concern regarding Medicare's consideration to implement a competitive acquisition program for suppliers of durable medical equipment. I work in at a hand center, which supplies a number of pre-fabricated splints to Medicare beneficiaries. The implementation of this type of program would not allow trained professionals, such as occupational and physical therapists, to supply these types of splints. These elderly patients may result in the risk of skin break down or other potentially adverse effects. For example, when providing a prefab wristhand-orthosis for the conservative treatment of carpal tunnel, the metal stay should be placed in a straight (or neutral) position to minimize stress on the median nerve. Pre-fabricated splints typically position the wrist at 30 degrees of extension. Having this type of splint provided by a nontherapy provider may cause harm to the median nerve and exacerbation the patients symptoms. This may result in more health care dollars spent to address potential problems created by not allowing rehabilitation professions to provide pre-fabricated splints.

Please consider allowing occupational and physical therapists to provide pre-fabricated splints to Medicare patients. Many of these patients need training and instruction on splint care and precautions that may not be provided with a centralized DME provider.

Thank you for your time and consideration.

Sincerely,

Ann Porretto-Loehrke, PT/CHT/COMT
Physical therapist/Certified Hand Therapist



Hand and Upper Extremity Center of Northeast Wisconsin, Ltd.



2323 N. Casaloma Drive P.O. Box 7700 Appleton, WI 54912-7079

June 19, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to express my concern regarding Medicare's consideration to implement a competitive acquisition program for suppliers of durable medical equipment. I work in at a hand center, which supplies a number of pre-fabricated splints to Medicare beneficiaries. The implementation of this type of program would not allow trained professionals, such as occupational and physical therapists, to supply these types of splints. These elderly patients may result in the risk of skin break down or other potentially adverse effects. For example, when providing a prefab wristhand-orthosis for the conservative treatment of carpal tunnel, the metal stay should be placed in a straight (or neutral) position to minimize stress on the median nerve. Pre-fabricated splints typically position the wrist at 30 degrees of extension. Having this type of splint provided by a nontherapy provider may cause harm to the median nerve and exacerbation the patients symptoms. This may result in more health care dollars spent to address potential problems created by not allowing rehabilitation professions to provide pre-fabricated splints.

Please consider allowing occupational and physical therapists to provide pre-fabricated splints to Medicare patients. Many of these patients need training and instruction on splint care and precautions that may not be provided with a centralized DME provider.

Thank you for your time and consideration.

Sincerely,

Troy Gutzman, OTR/CHT/CEES Hand Therapy Manager

(209-2)

June 19, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to express my concern regarding Medicare's consideration to implement a competitive acquisition program for suppliers of durable medical equipment. I work in at a hand center, which supplies a number of pre-fabricated splints to Medicare beneficiaries. The implementation of this type of program would not allow trained professionals, such as occupational and physical therapists, to supply these types of splints. These elderly patients may result in the risk of skin break down or other potentially adverse effects. For example, when providing a prefab wristhand-orthosis for the conservative treatment of carpal tunnel, the metal stay should be placed in a straight (or neutral) position to minimize stress on the median nerve. Pre-fabricated splints typically position the wrist at 30 degrees of extension. Having this type of splint provided by a nontherapy provider may cause harm to the median nerve and exacerbation the patients symptoms. This may result in more health care dollars spent to address potential problems created by not allowing rehabilitation professions to provide pre-fabricated splints.

Please consider allowing occupational and physical therapists to provide pre-fabricated splints to Medicare patients. Many of these patients need training and instruction on splint care and precautions that may not be provided with a centralized DME provider.

Thank you for your time and consideration.

Sincerely,

Donna Nennig, OTR Registered Occupational Therapist Dand & Upper Extremity Center of NE WH 209-3 2323 N. Casalone Dr. Oppleton, W. 54912-7079

June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to express my concern regarding Medicare's consideration to implement a competitive acquisition program for suppliers of durable medical equipment. I work in at a hand center, which supplies a number of pre-fabricated splints to Medicare beneficiaries. The implementation of this type of program would not allow trained professionals, such as cocupational and physical therapists, to supply these types of splints. These elderly patients may result in the risk of skin break down or other potentially adverse effects. For example, when providing a prefab wrist-hand-orthosis for the conservative treatment of RA, an ill fitting prefab splint may position the hand incorrectly increasing the deformity, resulting in increased pain and potentially causing more damage to the joints. This may result in more health care dollars spent to address potential problems created by not allowing rehabilitation professions to provide prefabricated splints.

Please consider allowing occupational and physical therapists to provide pre-fabricated splints to Medicare patients. Many of these patients need training and instruction on splint care and precautions that may not be provided with a centralized DME provider.

Thank you for your time and consideration.

Sincerely,

Laurie Green, OTR/CHT

Occupational Therapist/Certified Hand Therapist

ALVARADO ORTHOPEDIC MEDICAL GROUP, INC.

5555 Reservoir Drive, Suite 104, San Diego, CA 92120-5198 Medical Office: 619-286-9480 Facsimile: 619-286-4568 Business Office: 619-286-6930



John G. Finkenberg, M.D. Mark D. Jacobson, M.D. James E. Bates, M.D. Scott A. Hacker, M.D.

Eric R. Horton, M.D.

June 19, 2006

Emeritus Thomas D. Petersen, M.D. LeRoy W. Hunsaker, M.D. Roscoe F. Suitor, M.D. Steven A. Orcutt, M.D.

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other issues; Proposed Rule (CMS-1270-P)

To Whom It May Concern:

I write in regard to the above-captioned proposed rule ("Proposed Rule") and on behalf of Alvarado Orthopedic Medical Group, Inc. This is a multi-physician practice located in San Diego, CA. In June 2005, the Group obtained a Medicare DMEPOS supplier number. The sole purpose for doing so was for the Group to be able to furnish off-the-shelf (OTS) orthotics and braces, to our patients. Being able to offer these products and supplies directly to our patients is a significant benefit for our patients. Unfortunately, the Proposed Rule may undermine the ability of the Group to be able to continue to supply OTS orthotics, and braces to its Medicare beneficiary patients. I write to express my opposition to this possibility and to explain why I believe that this would be ill advised.

1. To begin with, physicians being direct suppliers of OTS orthotics and braces, is consistent with other Medicare policy on the issue. In January of 2001, the Centers for Medicare and Medicaid Services ("CMS") published final regulations implementing the Ethics in Patient Referrals Act (commonly known as the Stark Act). As you know, the Stark Act generally prohibits physicians from referring patients to entities with which the referring physician has a financial relationship for the provision of "designated health services," including orthotics and supplies. There are, however, several significant exceptions to this prohibition,

including an exception for certain designated health services provided by a physician to the physician's patients in the physician's office (i.e., the In-Office Ancillary Services Exception). 42 C.F.R. & 411.355(b). The In-Office Ancillary Services Exception evidences the federal government's recognition of the importance of providing continuous, high-quality health care services to patients directly from medical practices. In January of 2001, CMS confirmed that the In-Office Ancillary Services Exception was available for orthotics and related supplies furnished to Medicare beneficiaries and Medicaid beneficiaries and Medicaid recipients by there treating physician. In other words, a treating physician may provide and bill Medicare and Medicaid for orthotics and related supplies, so long as those services are ancillary to the underlying professional services and are provided in the same building where the physician provides substantially all of his/her professional services or in a centralized building where the physician provides ancilliary services. See Fed. Reg. 856,932 (Jan. 4, 2001) ("Prosthetics, prosthetic devices, and orthotics may be provided to a patient by a physician under the in-office ancillary services exception...")

CMS's position regarding the provision of orthotics pursuant to the In-Office Ancillary Services Exception is consistent with sound public policy. A physician should not be prohibited from providing his/her patients with medically necessary orthotics and related supplies at the time and place of service. To the contrary, I want to be absolutely certain that patients receive the correct items and proper fittings. Additionally, it is inconvenient for patients to be forced to travel to a "designated supplier" in order to receive ancillary products which are readily available from this office, at the same price as offered by a "designated supplier."

2. While I understand that Congress has mandated that the Secretary of Health and Human Services ("Secretary") must develop a competitive acquisition program for certain DMEPOS items and services. I also note that Congress afforded the Secretary exception authority for, among other things, "items or services for which the application of competitive acquisition is not likely to result in significant savings. 42 U.S.C. & 1395w-3(a)(3)(B). Similarly, the statute, 42 U.S.C. & 1395w-3(b)(6)(D), requires the Secretary to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section." Based upon the foregoing, to ensure patient convenience, I would encourage the Secretary to: (a) carve-out OTS orthotics, braces and casts from the competitive bidding program; or (b) if that is not an option, continue to allow physician suppliers, such as the Group, that are willing to supply OTS orthotics, braces and related supplies to their Medicare beneficiary patients at the rates determined through the competitive bidding program.

As a threshold manner, OTS orthotics should be carved-out of the competitive bidding program. CMS' own empirical evidence establishes that OTS orthotics account for a negligible percentage of eligible DMEPOS charges. See 71 Red. Reg. 25654, 25691 (Table 10)(May 1, 2006). Indeed, when combined, lower limb, spinal and upper limb orthoses accounted for only 2% of DMEPOS allowable charges in 2003. 71 Fed. Reg. at 25691 (table 10). Accordingly, competitive bidding for OTS orthotics is not likely to result in significant savings for the Medicare program and will lead to more inconvenience for Medicare beneficiaries.

If the Secretary is unable or unwilling to carve-out OTS orthotic from the competitive bidding program then, in an effort to accommodate small suppliers, the Secretary should afford physicians that only furnish DMEPOS to their patients in accordance with the In-Office Ancillary Services Exception (like the Group) the opportunity to continue to furnish such items in accordance with the prices determined by the competitive bidding program. Effectively, the Secretary would establish an "any willing provider" program for the physicians seeking to furnish DMEPOS to their Medicare beneficiary patients. The Secretary's alternative for accommodating small suppliers – i.e., through the establishment of networks for bidding purposes – is untenable for physician suppliers. The Stark Act would effectively preclude the formation of such networks by physician suppliers who refer their Medicare beneficiary patients to those network suppliers for DMEPOS as those networks could not operate within the parameters of the In-Office Ancillary Services Exception. Physician suppliers that otherwise provide quality items and services to their patients should not be unfairly excluded from continued participation in the Medicare program as DMEPOS suppliers.

We appreciate you careful consideration of our position.

Sincerely,

Fracy L. Maghato

Administrator



LA CASA DEL CONVALECIENTE, INC.

PO Box 9066366, San Juan, P.R. 00906-6366 Ave. De Diego #759, Caparra Terrace, San Juan, P.R. 00921 ● Tel. (787) 774-0800 ● Fax (787) 774-0814

Compañía Acreditada por: "Joint Commission" Estandarte de Oro por Calidad en Suidado de Salud

(211-0 (4)

June 20, 2006

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P. O. Box 8013 Baltimore, MD 21244-8013

Dear Sirs:

I'm writing this letter to express one of the reasons why we should not considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another relevant aspect to consider is that the Allowed Charges used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico witch were higher than in the States due to the recognition of the added cost involved importing. DME suppliers now have to absorb these previous added costs, therefore the use of allowed Charges of 2004 does not reflect the current reality of Allowed Charges in Puerto Rico, with the PAPC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

Thank you for attention.

Carlos Iglesias Gereral Manager

Rehabilitation Medical Supply, Inc.

Bayamón Tel. 779-1681 Fax: 995-3761 Arecibo: Tel. 878-2915 Fax: 878-2917



Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P.O. Box 8013 Baltimore, MD 21244-8013

June 23, 2006

Dear Sirs:

The Allowed charges to Puerto Rico were higher than in the States due to the recognition of the added cost involved in importing DME Supplies, such as local importation taxes, shipment and transportation expenses, and freight insurance charges, but in year 2005 this Fee Schedule was reduced by CMS and presently the DME suppliers have to absorb this previous added costs.

Is important to notice that the allowed charges used by PAPC to select the Metropolitan Statistic Area in the Competitive Bidding Program for 2007 was the 2004 Fee Schedule, which does not reflect the relevant reduction effective year 2005.

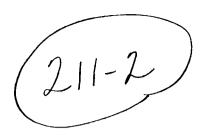
I strongly believe that this mistake does not make us eligible to be in the first 10 places for the initial face implementation of the Competitive Bidding.

Cordially,

Loida Ronda Cruz

Customer Service Department





23 June, 2006

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P

PO Box 8013

Baltimore. MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 1.0 MSA's (Metropolitan Statistic Ar(.a),

Another relevant aspect to consider is that the Allowed Charges used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico which were higher than in the States due to the recognition of the added costs involved in importing DME supplies, such as local importation taxes, shipmenthransportation expenses and freight-insurance charges, but in 2005 this fee schedule was reduced by CMS and presently the DME suppliers now have to absorb these pre' ious added costs, therethre the use of Allowed Charges of 2004 does not reflect the current reality of Allowed Charges in Puerto Rico, wish the PAPC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

William Juarbe

Presidente



Human Medical Supply, Inc.

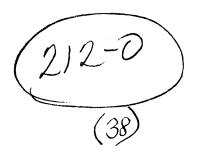
Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P.O Box 8013

I am writing this letter to express one of the reasons why we should not be considered in the Competitive bidding process or at least not considered in the first 10 MSA'S (Metropolitan Statistics Area).

Another relevant aspect to consider is that the Allowed Charge used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico were higher than the states due to the recognition of the added costs involved in. importing DME supplies, such as local importation taxes, shipment/transportation expenses and freightinsurance charges. In 2005 this fee schedule was reduced by CMS and presently the DME suppliers now have to absorb these previous added cost, therefore the use of Allowed Charges of 2004 does not reflect the current reality of Allowed Charges in Puerto Rico, with the PAPC is using to select the MSA's that are to be included in the initial phase of the program in 2007.



CALLE ANDRES MENDEZ LICIAGA # 6 SAN SEBASTIAN PUERTO RICO, 00685



Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.



Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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Sincerely,

Juan A Roman

Manager



Calle Muñoz Rivera # 9 San Sebastián, PR 00685

(212-2)

Q Med Equipment Enterprises, Inc.

Calle Muñoz Rivera # 136 Guayanilla, P.R. 00656



Tel. (787) 835 - 7311 Fax. (787) 835 - 7451 (787) 309 - 6091

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

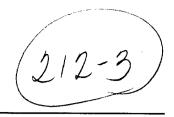
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Martin Ulyan Prosident



GB FAMILY HEALTHCARE, INC.



Calle Amistad #8, Lajas, PR 00667 · Tel./Fax (787) 899-7884

June 23, 2006

Center For Medicare & Medicaid Services
Department Of Health And Human Services

Attention: CMS - 1270P

PO Box 8013

Baltimore, MD 21244-8013

Dear Sirs.

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Sincerely,

Manager



EXCELLENT CARE MEDICAL SUPPLY

P.O. BOX 3419 LAJAS, P.R. 00667 TEL:/FAX.(787)851-0757 (212-4)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

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EAR



Materiales y Equipos para Médicos y Convalecientes VENTA • ALQUILER • SERVICIO

212-5

June 23, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270P P. O. Box 8013

Baltimore, MD 21244-8013

Dear Sire,

The I am writing this letter to express one of the reasons why should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Mctropolitan Statistic Area).

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Rafel A Viera President

#456439000





(212-60)

Center of Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

June 22, 2006

Dear Sirs:

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many supplies and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

Armando Ballart

President of Service Medical Equipment Inc.

gollos Ballon



Biomedical Services, Corp.

PO Box 902 San Sebastián, PR 00685

Tels: (787)896-0973 / (787)636-7467) Fax: (787)896-6464



Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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Sincerely,

Carlos I Villahermosa

President



Paradise West Medical, Inc.

Venta y Alquiler de Equipos Médicos
"Hacemos la diferencia como su nueva Fuente de Servicios".

Marginal Urb. Sullana, Calle Jenerife #11, Mayagüez, P.R. 00681 Tél. & Fax (787) 833-1870 (212-8) os".

June 23, 2006

Sra. Marisel Rivera, Proprietary

Re: Paradises West Medical, Inc.

#Provider: <u>5140390001</u>

Center for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270P

P. O. Box 8013 Baltimore, MD 21244-8013

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COQUI MEDICAL EQUIPMENT, INC. BO. ASOMANTE CARR. #14 KM. 47.6 AIBONITO, PR. 00705 787-991-0075



Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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(212-10.)

Center of Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

June 22, 2006

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Norma Ballart

Vice-president of Service Medical Equipment Inc.



Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

1314290002

Calle Andrés Mendez Liciaga #31 San Sebastián, P. R. 00685

Alquiler y Venta de Equipo Médico

Tel. 280-1390

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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Jun. 27 2006 09:22AM P1

212-13

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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American Redical Equipment Colle Mateo Fajardo #16 Hormigueros P.Z. 00660 787-849.2085



GARNELL Medical Equipment, Corporation

PO BOX 7313 MAYAGÜEZ, PUERTO RICO 00681-7313

212-14

June 23, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
P.O.BOX 8013
Baltimore, MD 21244-8013

Dear Sirs:

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Sincerely Yours

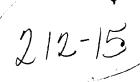
Nellie García

President

(787) 806-2222
Garnell Medical Equipment, Corporation
P.O. Box 7313
Mayaguez, Puerto Rico 00681-7313



Paradise Medical Supply, Inc.





June 23, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270P

P. O. Box 8013

Baltimore, MD 21244-8013

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Myria Kivera

tider Num. 4308950001



Human Medical Supply, Inc.

(212-14)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO BOX 8013
Baltimore, MD 21244-8013

Dear Sir,

I am writing this letter to express one of the reasons why we should not be considered In the Competitive bidding process or a least not considered in the first 10'MSA's (Metropolitan Statistic Area).

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NORMA WILLIAMS





23 June, 2006

Center for Medicare & Medicaid Services Department of Health and Human Services

Attention: CMS-1270P

PO Box 8013

Baltimore. MD 21244-8013

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William Juarbe

Presidnet

EQUIPOS MEDICOS DEL SUR, INC.

Mattei Lluberas #52 Yauco, P.R. 00698 Teléfono / Fax (787) 856-3403 212-18

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

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5/2-1.11



LA CASA DEL CONVALECIENTE, INC.

PO Box 9066366, San Juan, P.R. 00906-6366 Ave. De Diego #759, Caparra Terrace, San Juan, P.R. 00921 ● Tel. (787) 774-0800 ● Fax (787) 774-0814

Compañía Acreditada por: "Joint Commission" Estandarte de Oro por Calidad en Cuidado de Salud

June 20, 2006

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P. O. Box 8013 Baltimore, MD 21244-8013

Dear Sirs:

I'm writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

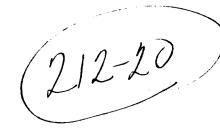
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Thank you for your attention.

Sincerely,

Carlos Iglesias General Manager

Emilio O. Vincenty-Asad Provider P.O. Box 1903 Mayagüez, P.R. 00861



To: Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-12070P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or at least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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Truly Yours,

EMILIO O. VINCENTY-ASAD

13/06



Advanced Rental & Sales Medical Equipment, Inc.

PO Box 336839 Ponce, P.R. 00733 - 6839 Tel. (787) 844-4123

(212-21)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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Cordially; ,

Wilfredo Lopez
President

 $P_{\text{rofessional Health Care \& Hospital Supply}}$

Calle Colón #131, Aguada, PR 00602 TEL: 787-252-3945 Fax: 787-252-3940

2006-06-26

Centers for Medicare

Medicaid Services

Department of Health and Human Services

Attention: CMS-127P

P.O. Box 8013

Baltimore, MD 21244-8013

Dear Sirs:

I am writing this letter to express one of the reasons why we should not be considered In the competitive bidding process or at least not considered in the first 10 MSAs (Metropolitan Statistic Area).

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Respectfully yours,

Damaris Matos Acevedo

President



(212-23)

Center for Medicare and Medicaid Services Department of Health and Human Service Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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Sincerely,

Norali Rodriguez

General Manager/Owner



FARMACIA HEIDI CALLE COLON #260 AGUADA, PR 00602

TEL. 787-868-3710 FAX 787-868-2940

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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FARMACIA HEIDI

Calle Colón #260 Aguada, P. R. 90602

13142900/

LE MEDICAL & HOSPITAL SUPPLY, INC.

212-25

MARGINAL FAGOT #N42 PO BOX 34069 PONCE, PUERTO RICO TEL. (787)841-3033 FAX (787)812-5384

JUNE 28, 2006.

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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CORDIALLY

Hiram Rivera - President

(212-26)

MOCA HOSPITAL SUPPLY PO BOX 1198 CARR 444 KM 7.3 BO ROCHA MOCA, P R 00676 TELEFONOS: 787 877-1010 787 818-1069

Center for Medicare & Medicaid Services Departamen of Health and Human Services] Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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Sincerely yours,

José E. Colón Santiago

gone Exil of



P.O. Box 207 Hormigueros, Puerto Rico 00660

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

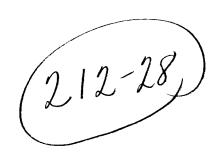
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. David Rivera López

Solution Medicos Medic



LOPEZ MEDICAL EQUIPMENT, INC. CALLE DR. PEDRO ALBIZU CAMPO # 81 P.O BO X 1350, LARES, P.R. 00669 TEL. (787)897-0978 FAX (787)897-3560

23 de Junio de 2006

Center for Medicare & Medicaid Services Department of Health and HumanServices Attention: CMS-1270 P P.O Box 8013 Baltimore, MD 21244-8013

Dear Sirs,

Then I am writing this letter to express one of the reasons why we should not be considered in the Competitive bidding process or a least not considered in the first 10MSA'S (Metropolitan Statistic Area).

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133,901 ON THE PROPERTY OF THE

Propietary



212-29 PO Ma Tel:

P.O. Box 1750 Mayaguez, PR 00681

Tel: 787-834-2350

Ext. 6298
Fax: 787-831-6315

Center for Medicare & Medicaid Service Department of Health and Human Services Attention: CMS-1270P PO. Box 8013 Baltimore, MD 21244-8013

Dear Sir's

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- Cama de Posición
- Sillón de Ruedas
- Inodoro Portátil
- Andador
- Muletas
- Concentradores de Oxígeno
- Matre de Aire
- Bastón de Cuatro Puntos
- Máquina de Terapia Respiratoria
- Glucómetro
- Bastón Sencillo
- Trapecios
- Tracheal Care Kit
- Máquina de Succión
- Pads y
 Compresor
 de Aire
- Implementos de Enfermería
- Y Otros Servicios

(212-30)

Porta Coeli Medical Supply #12 Bajos Calle Esperanza P.O. Box 1772 San Germán, PR 00683 Tel/Fax: (787) 892-1553 Cel: (787) 375-0398

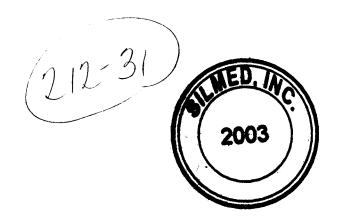
Center for Medicare & Medicaid Services Department of Health and Human Services Att: CMS-1270P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Sirs,

It is our interest through this letter you might understand the reasons why we should not be in first 10 MSAs (metropolitan Statistic Area) or in the competitive bidding process.

An important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given that the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

Leomarie Pabón Manager



Dilmed, Inc. PO Box 7990, PMB121 Hayaguez PR 00G81

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

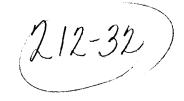
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Center for Medicare & Medicaid Services
Department If Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013



June 22, 2006.

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Thank for lets express our opinion about this situation.

Mrs. Aleinés Valentín Núñez

President



Krystal Medical Equipment 212

VENTA Y ALQUILER DE EQUIPO MEDICO Y MUCHO MAS...

Calle Ramos Antonini #155-E Mayagüez, PR 00680 Tel./Fax: (787) 805-6325 - Cel.: (787) 344-6639

Center for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

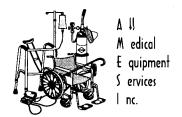
Cordially,

Eneida Villarrubia, RN., MSN.

President

June 21,2006

"Supera Barreras te ayudamos a Vivir Mejor"



M edical E quipment Services, Inc. All Medical Equipment Services, Inc.

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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Herminia Cordero

President

Top Quality

Health Care Inc.

Carr. 119 Km 1.1 San German, P.R. 00683 Tel. 787- 892-4600 Fax 787-892-4620

Cel.787-309-5820

212-35

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

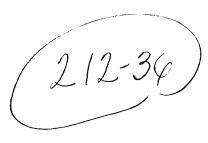
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Martin Ulgen President





Center for Medicare & Medicaid Services
Department of Health and Human Services
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Yours truly, Luis A. Orosena

President.

WESTSIDE MEDICAL SUPPLY

Calle Pavía Fernández # 67 San Sebastián P.R. 00685 Tel. (787) 280 6402 Fax (787) 896 1640 1 800 990 3232 (212-37)

Center for Medicare & Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244-8013

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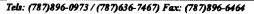
Juan A Roman

Manager



Biomedical Services, Corp.

PO Box 902 San Sebastián, PR 00685





Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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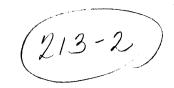
Sincerely,

Carlos I Villahermosa

President



Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P



Po Box 8013 Baltimore, MD 21244-8013

June 22, 2006.

Dear Sirs,

I am writing this letter to express of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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Thank for lets express our opinion about this situation.

President





Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P

PO Box 8013

Baltimore, MD 21244-8013

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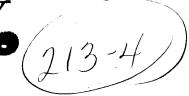
Yours truly, Luis A. Orosena

President.

Top Quality

Carr. 119 Km 1.1 San German, P.R. 00683

Tel. 787- 892-4600 Fax 787-892-4620 Cel.787-309 - 5300



Center for Medicare & Medicaid Services
Department of Health and Human Services
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PO Box 8013
Baltimore, MD 21244-8013

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Martin Ulyen President

(213-5)

Q Med Equipment Enterprises, Inc.

Calle Muñoz Rivera # 136 Guayanilla, P.R. 00656



Tel. (787) 835 - 7311 Fax. (787) 835 - 7451 (787) 309 - 6091

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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Math Mogan President



Krystal Medical Equipment
VENTA Y ALQUILER DE EQUIPO MEDICO Y MUCHO MAS...

Calle Ramos Antonini #155-E Mayagüez, PR 00680

Tel./Fax: (787) 805-6325 - Cel.: (787) 344-6639

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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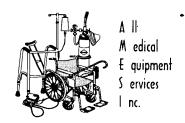
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President

"Supera Barreras te ayudamos a Vivir Mejor "



M edical Equipment Services, Inc.

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Department of Health and Human Services
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Minuus Cordero Herminia Cordero President





P.O. Box 1750 Mayaguez, PR 00681

Tel: 787-834-2350 Ext. 6298

Fax: 787-831-6315

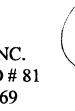
Center for Medicare & Medicaid Service Department of Health and Human Services Attention: CMS-1270P PO. Box 8013 Baltimore, MD 21244-8013

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- Cama de Posición
- Sillón de Ruedas
- Inodoro Portátil
- Andador
- Muletas
- Concentradores de Oxígeno
- Matre de Aire
- Bastón de Cuatro Puntos
- Máquina de Terapia Respiratoria
- Glucómetro
- Bastón
 Sencillo
- Trapecios
- Tracheal Care Kit
- Máquina de Succión
- Pads y
 Compresor
 de Aire
- Implementos de Enfermería
- Y Otros
 Servicios





LOPEZ MEDICAL EQUIPMENT, INC. CALL DR . PEDRO ALBIZU CAMPO # 81 P. O BOX 1350 , LARES, P.R. 00669 TEL. (787)897-0978/ FAX. (787)-897-3560

23 de Junio de 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS -1270P
P. O Box 8013
Baltimore, MD 21244-8013

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ARES BR

Cordially,

M. López Collazo



P.O. Box 207 Hormigueros, Puerto Rico 00660

Center for Medicare & Medicaid Services
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Attention: CMS-1270P
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109,080 P. German.

David Rivera Vópez

President

Sincerely,

MOCA HOSPITAL SUPPLY PO BOX 1198] CARR 444 KM 7.3 BO ROCHA MOCA, P R 00676

(213-11)

TELEFONOS: 787 877-1010 787 818-1069 FAX

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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Sincerely yours,

José E. Colón Santiago

WESTSIDE MEDICAL SUPPLY 213-12 Calle Pavía Fernández # 67

Calle Pavía Fernández # 67 San Sebastián P.R. 00685 Tel. (787) 280 6402 Fax (787) 896 1640 1 800 990 3232

Center for Medicare & Medicaid Services
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provided by Traditional Medica

LE MEDICAL & HOSPITAL SUPPLY, INC.

MARGINAL FAGOT #N42 PO BOX 34069 PONCE, PUERTO RICO TEL. (787)841-3033 FAX (787)812-5384 213-13/)

JUNE 28, 2006.

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

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Cordially

Hiram Rivera- President



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Sincerely,

Mrs. Norali Rodriguez General Manager/ Owner

(213-15)

Professional Health Care & Hospital Supply

Calle Colón #131, Aguada, PR 00602 TEL: 787-252-3945 Fax: 787-252-3940

2006-06-26

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-127P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Sirs:

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or at least not considered in the first 10 MSAs (Metropolitan Statistic Area).

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Respectfully yours,

Damaris Matos Acevedo

President



Advanced Rental & Sales Medical Equipment, Inc.

PO Box 336839 Ponce, P.R. 00733 - 6839 Tel. (787) 844-4123

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013



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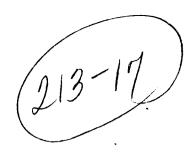
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Cordially;

Wilfredo lopez

President

Emilio O. Vincenty-Asad Provider P.O. Box 1903 Mayagüez, P.R. 00861



To: Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-12070P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or at least not considered in the first 10 MSA's (Metropolitan Statistic Area).

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Truly Yours,

EMILIO O. VINCENTY-ASAD

6/23/04



LA CASA DEL CONVALECIENTE, INC.

PO Box 9066366, San Juan, P.R. 00906-6366
Ave. De Diego #759, Caparra Terrace, San Juan, P.R. 00921 ● Tel. (787) 774-0800 ● Fax (787) 774-0814
Compañía Acreditada por: " Joint Commission " Estandarte de Oro por Calidado de Salud

June 20, 2006

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P. O. Box 8013 Baltimore, MD 21244-8013

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Thank you for your attention.

desico

Sincerely,

Carlos Iglesias General Manager EQUIPOS MEDICOS DEL SUR, INC.

Mattei Lluberas #52 Yauco, P.R. 00698 Teléfono / Fax (787) 856-3403

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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95/1.10





23 June, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1270P
PO Box 8013
Baltimore, SID ²1244-8013

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William Juarbe, President



Paradise Medical Supply, Inc.

213-21



June 23, 2006

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Myrya Kwera

Provider Num. 4308950001

EXCELLENT CARE MEDICAL SUPPLY

P.O. BOX 3419 LAJAS, P.R. 00667 FEL FAX (787)851-0757 213-22

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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EDD Co

GARNELL Medical Equipment, Corporation

PO BOX 7313 MAYAGÜEZ, PUERTO RICO 00681-7313

(213-23)

June 23, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
P.O.BOX 8013
Baltimore, MD 21244-8013

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Sincerely Yours.

Nellie García

President

(787) 806-2222
Garnell Medical Equipment, Corporation
P.O. Box 7313
Mayaguez, Puerto Rico 00681-7313



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Jan.



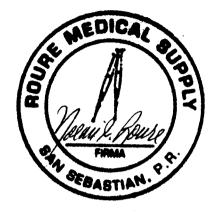
Calle Andrés Méndez Liciaga #31

San Sebastián, P. R. 00685

Tel. 280-1390

Alauiler v Venta de Equipo Médico

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013



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FARMACIA HEIDI CALLE COLON #260 AGUADA, PR 00602 TEL. 787-868-3710 FAX 787-868-2940

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FARMACIA HEIDI Calle Colón #260 Aguada, P. R. 00602

Israel Perez # 1314290001

(213-27)

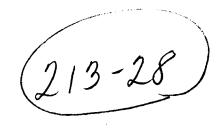
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Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

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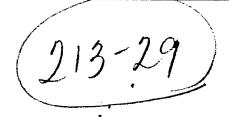
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Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013



June 22, 2006

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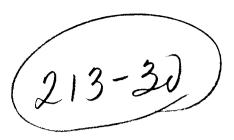
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Armando Ballart

President of Service Medical Equipment Inc.

Just Busin

COQUI MEDICAL EQUIPMENT, INC. BO. ASOMANTE CARR. #14 KM. 47.6 AIBONITO, PR. 00705 787-991-0075



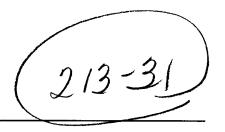
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Calle Amistad #8, Lajas, PR 00667 · Tel./Fax (787) 899-7884

June 23, 2006

Center For Medicare & Medicaid Services
Department Of Health And Human Services

Attention: CMS – 1270P PO Box 8013 Baltimore, MD 21244-8013

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Sincerely.

Ms. Jessica García

Manager







Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

(213-3.2)

June 22, 2006

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Norma Ballart

Vice-president of Service Medical Equipment Inc.



Materiales y Equipos para Médicos y Convalecientes **VENTA** • ALDUILER • SERVICIO

June 22, 2006

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Rafael A Viera Præsident

#456439000





Paradise West Medical, Inc.

Venta y Alquiler de Equipos Médicos

"Hacemos la diferencia como su nueva Fuente de Servicios".

Marginal Urb. Sullana, Calle Jenerife #11, Mayagüez, P.R. 00681 Tél. & Fax (787) 833-1870

William A

June 23, 2006

Sra. Marisel Rivera, proprietary

Re: Paradises West Medical, Inc.

Provider: <u>5140390001</u>

Center for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270P

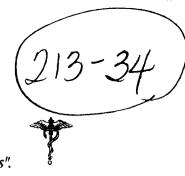
P.O. Box 8013

Baltimore, MD 21244-8013

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(213-35)

Porta Coeli Medical Supply #12 Bajos Calle Esperanza P.O. Box 1772 San Germán, PR 00683 Tel/Fax: (787) 892-1553 Cel: (787) 375-0398

Center for Medicare & Medicaid Services Department of Health and Human Services Att: CMS-1270P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Sirs,

It is our interest through this letter you might understand the reasons why we should not be in the first 10 MSAs (metropolitan Statistic Area) or in the competitive bidding process.

Long-standing relationships between beneficiaries and familiar suppliers will be interrupted, causing disruption in services and unsatisfied patients. Given Puerto Rico's location in the heart of the Caribbean Sea, the island is impacted yearly by hurricanes and tropical storms that make it impossible for distant suppliers to provide the services needed because of sudden flooding in many of the small, rural roads in the cast region of the island. These common events impact the beneficiaries' access to Porta Coeli Medical Supply, such as oxygen tanks, which are needed on a regular basis.

In conclusion, the result of implementing the Competitive Bidding Process would be that small, community-based suppliers would be displaced by larger chain suppliers that can take advantage of economies of sale, but which may not be in the interest of the beneficiaries. The Competitive Bidding Process will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so because although it is essential for the beneficiary to be entitled to continue under the label of "Traditional Medicare", they would not have the benefit of selecting from an array of suppliers, since only a few suppliers would be available to provide services. It is this freedom of selection, currently provided by Traditional Medicare, which should be safeguarded.

Leomarie Pabón

Manager

Sincerely.

(213-36)

Caribbean Home Medical Equipment, Corp

Venta y Alquiler de Equipos Medicos 8155 Calle Concordia Suite 104 Ponce, P.R. 00717-1599 Tel/Fax: (787) 284-5058

Center for Medicare & Medicaid Services

Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express that one of the reasons why we should not be considered in the competitive bidding process or at least not to be considered in the first 10 MSA's (Metropolitan Statistic Area); is as follows: i.e. the long-standing relationships between beneficiaries and familiar suppliers will be interrupted causing disruptions in the services and dissatisfaction for patients. Given Puerto Rico's location in the heart of the Caribbean Sea: the island is impacted yearly by hurricanes and tropical storms that makes it impossible for distant suppliers to provide the services needed, because of the sudden flooding in many of the small and rural roads in the cast region of the island. These common events impact the beneficiaries access to DME supplies, such as oxygen tanks that are needed on a regular basis. In summary, the result of the implementation of the Competitive Bidding Program would be that small. community-based suppliers would be displaced by larger chain of suppliers that can take advantage of economies of scale, but which may not be in the interests of beneficiaries. The Competitive Bidding Program will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so, because although in essence the beneficiary will be entitled to continue under the label of "Traditional Medicare", they would not have the actual benefits of selecting from an array of suppliers since only one or two suppliers would be available to provide the services. This is the freedom of selections that is currently provided by Traditional Medicare that must be vigilantly safeguarded.

Respectfully yours,

PEDRO A. SANTIAG

President

(214)

Centers for Medicare/Medicaid Services

Attention: CMS-270-P

RE: Low Vision Aid Exclusion

6116/06

Dear Sirs,

Ite are glad to hear you are Thinkis	19
about including "LOW VISION AIDS" in the	, Le
approved "medical equipment" rulings	1.
The were glad to see wheelchairs, crutches	
and bathroom aids approved, Having	
CCTV'S, magnifiers and other aids will	
help keep mare of us in our homes, especie	
those who cannot afford them on	0
their own.	
I belong to a "vision loss suppor	t
group". Some of the members could	•
be as independent as theef are withou	
their magnifiers, CCTV's and special	2
glasses.	
Please couxider this request.	
Natalie S. Riecks	





Independent Medical Co-op, Inc.

129 Executive Circle Daytona Beach, FL 32114

386,258,1530

Fax 386.258.1525 www.imcoinc.com info@imcoinc.com

DATE:

June 26, 2006

TO:

Centers For Medicare & Medical Services

Department of Health and Human Services

Attention: CMS-1270-P

Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

FROM:

Deb Bullock

IMCO

Vice President of Acute Care & LTC Markets

REFERENCE:

Competitive Acquisition Program for Certain DMEPOS

and other Issues. (42 CFR Parts 411, 414 and 424)

IMCO is a healthcare distribution association representing approximately 70 DMEPOS distributors nationally. Their customer base includes over 500 skilled nursing facility providers.

IMCO and our membership is opposed to the inclusion of "any willing provider" environment to include skilled nursing facilities. Requiring SNF's to competively bid is fraught with concerns:

- 1. The competitive bidding demonstration has not been successfully conducted in skilled nursing facilities.
- 2. Nursing facility patients require a higher level of care than non-residents:
 - Care plans could be interrupted as a result of competitive bidding putting patients at risk.
 - Patient access to quality products could be compromised resulting in serious or life threatening complications and increased cost of care.
- 3. "Cost in Use" analysis is not considered
 - Many products appear to be less expensive however, in use they require either additional or replacement products.





Englewood Health Care Center (214)

Amber McDonald, Administrator

June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Englewood Health Care Center, LLC. Englewood is located in Monroeville, Alabama. Englewood is licensed for 87 Medicare/Medicaid beds providing services such as skilled nursing care including physical therapy, occupational therapy, and speech therapy. Englewood also offers Restorative programs, an activity program and Social Services. Englewood employs on average 120 employees.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Englewood we have numerous residents whose care could be interrupted as a result of this implementation - jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Amber McDonald Administrator

(217)

BARR PHARMACY BLAIR MEDICAL SUPPLY 1651 WASHINGTON STREET BLAIR, NE 68008 6-27-06

CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES ATTENTION CMS-1270-0 P.O. BOX 8013 BALTIMORE, MD 21244-8013

RE: CMS-1270-P

DEAR SIR OR MADAM:

I appreciate the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments.

Competitive Bidding

The proposal that would require beneficiaries to obtain replacement supplies through designated providers I feel restricts the beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Opportunity for Participation by Small Supplies

CMS needs to take steps to ensure that small suppliers can participate in the program. We need to be allowed to designate a smaller market in which to provide DMEPOS.

I feel that any small supplier willing to accept the single payment amount that CMS has established should be allowed to join the program as a contracted supplier.

Beneficiaries should have convenient access to the DMEPOS supplies they need. Not every beneficiary lives in or close to a metropolitan or large city.

We currently provide oxygen, wheelchairs, beds, walkers, ostomy supplies, medication and diabetic supplies in our pharmacy and without these revisions to the final regulation, I will be unable to continue providing these valuable services to our patients.

I strongly urge you to revise the regulation so that small suppliers can continue to meet the needs of the patients in our smaller and rural communities. Each beneficiary should have the right to chose where they go as long as the supplier is a willing provider.

Thank you for considering my view.

Sincerely, M. Charles & Barr, R.P.

Dr. Charles C Barr, R.P.

(218)

Department of Health and Human Services

Attention: CMS-1270-P Mail Stop *C4-26-05* 7500 Security Boulevard Baltimore, MD 21244-1850

Via Overnight Delivery

Re:

Comments to Proposed Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS"), File Code CMS-

1270-P

Dear Sir or Madam:

These comments are submitted on behalf of Patient Support Services, Inc. ("PSSI"). PSSI is an accredited small business located in Texarkana, Texas that provides enteral nutrition to patients in Texas, Arkansas, and Oklahoma. PSSI is a niche provider of enteral nutrition and related supplies. The provision of enteral nutrition products makes up ninety-five percent of the company's business. PSSI submits these comments in response to the proposed rule related to competitive acquisition of DMEPOS products published in the Federal Register 011 May 1, 2006.

I. Criteria for Item Selection

Enteral nutrition is an area in which poor service by the DMEPOS supplier can seriously affect patient care. There are no fewer than 100 different types of enteral nutrition products on the market. Although the products vary in the number of calories provided to the patient, the differences do not stop there. Enteral nutrition products contain different concentrations of nutrients and vitamins and the supplier of enteral nutrition must be knowledgeable about and able to provide the formula as prescribed. On more than one occasion, PSSI has been contacted by a discharge planner to take over the provision of enteral products for a patient who had been receiving services from a provider that represented itself as knowledgeable and capable of providing enteral nutrition. Oftentimes, companies that have the experience to provide other types or DME represent themselves as enteral nutrition providers when in reality they have insufficient expertise to provide enteral nutrition products. When the enteral nutrition provider does not have the requisite knowledge about enteral nutrition, the caregivers to the patient are unable to get the guidance and product they need. PSSI's small business structure and emphasis on quality has made it the enteral supplier of choice for a number of discharge planners who have worked with larger companies.

Many patients and residents of Skilled Nursing Facilities (SNFs), long term care facilities, and nursing homes require enteral nutrition. Oftentimes, the supplier of enteral nutrition for the residents of these facilities is selected by the facility. Many enteral nutrition

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companies have agreements with SNFs; long-term care facilities and nursing homes to act as their supplier for enteral nutrition products. In choosing a supplier, the facilities look for the best quality of service. As written, the proposed regulations require that all SNFs either become contract suppliers or utilize contract suppliers for the provision of DMEPOS. The regulations further require that residents of long term care facilities and nursing homes obtain supplies only from contract suppliers, unless the grandfathering provision applies. PSSI believes that this approach will prove to be problematic, especially in the area of enteral nutrition and recommends that enteral nutrition be excluded from competitive bidding altogether as was the case in the San Antonio demonstration project and the second and final round of bidding in the Polk County demonstration project

Under the grandfathering provisions, it appears that a SNF, long term care facility, or nursing home may be able to continue to use its former enteral nutrition supplier if it chooses to do so. What is unclear, however, is whether a SNF, long term care facility, or nursing home may continue to use that same supplier for all of *its* patients, including new residents who arrive at the facility after the contract suppliers are determined.

SNF patients as well as long term care patients who require daily attention and care should have the opportunity to use the services of a DMEPOS company that has proven itself to be effective, reliable and responsive to the needs of patients in fragile health. Because of the uniqueness of enteral nutrition services as well as the potential impact competitive bidding can have on the quality of enteral nutrition services available to patients, PSSI further recommends that, at a minimum, a demonstration project which reviews the effect of competitive bidding on the provision of enteral supplies be completed prior to widespread implementation.

II. Regulatory Impact Analysis

Under the new competitive bidding regulations, it is likely that small businesses such as PSSI that have built their companies on quality care will be unable to compete against large companies and small businesses that claim to provide enteral nutrition but do not have the resources to do so. Although many companies may claim that they are capable of providing enteral nutrition, few have invested in the knowledge and expertise required to supply enteral nutrition properly. The physicians and nurses at each SNF, long term care facility, and nursing home are the best persons to determine and recommend those suppliers that provide the best quality service.

One way to reduce the impact of competitive bidding on small business suppliers and to protect patient choice is to allow any supplier who submits a bid, and who is willing and able to provide the product for the competitive bidding price, to participate as a contract supplier

In the preamble to the proposed regulations; it is explained that the regulation specifically does not allow any willing supplier to provide a competitively bid product, even if that provider is wilting to accept the contract price. The reason provided in the <u>Regulatory</u> Impact Analysis is

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that the statute requires a company to have submitted a bid in order to be a supplier. This rationale does not take into consideration those companies that submit good faith bids but are not awarded contracts. The statute does not prevent the Secretary from naming any bidding supplier willing to provide product at the competitive bid price as a contract supplier. Allowing small businesses to participate in this manner after submitting a good faith bid will allow for the participation of more small businesses as mandated by the statute, and will allow for more patient choice. The presence of more businesses competing to serve patients at the competitive bidding price will ensure that the patients receive better quality care from their DMEPOS supplier.

III. Opportunity for Participation By Small Suppliers

At the present time, at least 90% of the suppliers of DMEPOS are small businesses. Under the program outlined in the proposed regulation, large corporations will have an enormous advantage. If the regulation is implemented as proposed, small businesses will very likely cease to be the norm in the DMEPOS industry. It should be anticipated that in an effort to compete with the big companies, some small businesses will submit bids below the prices they can afford. This will at a minimum affect the quality of the small companies' services, and will most likely cause a large number of small businesses to fall into financial ruin. While the regulation does provide small companies with a networking option, it is unlikely that such an option will be enough to assure that small businesses will survive under competitive bidding. If anything, it is more likely that the networked small companies, if successful, will eventually become a single large company. Creating a single large company will not assure the participation and protection of small suppliers as required by the Medicare Modernization Act.

In order to provide small businesses with the opportunity to compete in a competitive bidding area, PSSI proposes that the Secretary implement procedures which have been in existence in the federal government for many years. The government should set aside a certain portion of competitive bidding slots solely for small business. Small business set-asides have been used under the Federal Acquisition Regulation procedures for many years and have helped to provide small business opportunities within the government contracting realm.

Small businesses face even greater threats if they do not receive special consideration under the competitive bidding regulations than they face in typical government contracting. In most industries, there is a market for the services rendered by the small businessperson outside of the competitive bidding arena. Unfortunately, for many DMEPOS products, Medicare represents by far the largest portion of the market. If a small business does not win the opportunity to serve as a contract supplier during the initial competitive bidding process, then it is likely that the company will cease to exist. Thus, during the second round of competitive bidding, there will be no new companies to join the ranks of competition. With no new competition, the government will be forced to accept higher bids from the remaining large companies during the second competitive bidding cycle three years later. Because many small

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DMEPOS suppliers will not be able to survive without Medicare business, the cost savings achieved through competitive bidding will be short-lived.

Thank you for taking the time to review my comments.

Sincerely,

Mike Conway President

PSK/sk

CHRIS ALBRITTON, D.P.M. Podiatrist -- Foot Specialist

2501 South Willis Suite A Abilene, Texas 79605 325-695-8990

Centers for Medicare & Medicaid Services Department of Health and Human Services wingfoot@affcpodiatry.com www.affcpodiatry.com Fax: 325-695-0901

June 27, 2006

(219)

Diplomate, American Board of Podiatric Surgery Board Certified in Foot Surgery

Fellow of the American College of Foot and Ankle Surgeons

Chief of Staff, Hendrick Center for Extended Care

P.O. Box **8**013 Baltimore, MD 21244-8013

Attention: CMS-1270-P

Mark B. McClellan, MD. PhD

Dear Dr. McClellan:

Administrator

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required instead to bid to supply my entire Metropolitan Statistical Area (MSA), my patients will be negatively impacted.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only, and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items, and the most frequent item I use is a Cast Walker (walking boot). Mrs. JH is a delightful, spry, 78 year old female who loves to walk for exercise. She presented to me with pain and swelling in her left foot, and stated she could no longer walk for exercise. This was extremely distressful to her, because she has coronary artery disease, as well as Peripheral Arterial Disease, and continuing her walking program is vitally important to her health. After examination and x-rays, I diagnosed her with a fracture of her 2nd metatarsal bone in her left foot, associated with osteoporosis. I placed her into a Cast Walker (a DMEPOS item dispensed from my office), increased her calcium intake, and in 4 weeks, she was able to resume her walking program at 50%.

If I no longer function as a supplier, these patients will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. Being unable to bear full weight on the injured extremity places these patients at high risk of falls, which so often results in other additional injuries, such as hip fractures, forearm fractures, and shoulder injuries. If I am not a supplier in the new program, my patients will suffer.

Please change the physician definition from 1861(r)(1) to 1861(r) so that my patients will continue to be able to receive from me the medical care and medical products that they need.

Sincerely,

Chris Albritton, DPM





Mitchell R. Waskin, D.P.M., FACFAS

(804) 320-FOOT (3668) (804) 320-2600 (Fax)

1465 Johnston-Willis Drive Richmond, VA 23235

www.3204.OOL.com

June 26, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P Mail Stop: C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Attention: CMS-1270-P Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) **FROM** 1861(r)(1) **TO** 1861(r)(3).

Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items *to my patients only* and the right to execute a physician authorization. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program.

Sincerely,

Mitchell R. Waskin, D.P.M., FACFAS

Foot & Ankle Center, L.L.C. 1465 Johnston-Willis Drive Richmond, Virginia 23235

(221)Centers for Melicare and Medicaid Services 1/2 Department of Health and Human Services Attention: CMS-1270-P PU BOX 8013 Baltimore, MD 21244-8013 Bryan Wodask! Occupational Therapset 6-26-06 1005 Brown Ave Comberland MD 21502 301-724-9114 Hear Sir or Madam, I an un occupational therapust who is a. certified hand theragest. I see dozens of patients sach day in my ontpalient clinic many have ocute donditions of west, hand, ellow and shoulder as well as nech & wack problems. As a result of læis injuries, changes can be rather ragid. a case of tendontes sudder gloorsens a cut landon is repaired but accidently suptured by the pateent. Or perhaps a nerve is inflamed and requires a depperent splint de léduce pressure on tre area. All take flexibility in treatment by me the therapest as well as the doctor. proposed would not allow me to make his adaptation to a changing injurye or problem. Problems which fan Kead to

disability or prolong tereatment and increase orerall costs all strasis are provided based on needs which change. Our clinical shills allow us to make informed decisions for the Correct orthosis This proposal may place is in a position where I need to do line right thing ethically but my pand will be teed. The savings of bidding Off the shelf orthosis will be small as medicare Whelf has stated but the locks to the guttents will be significant and to medicare andll. I have seen inappropriate splints given that dan Cimit Anotion and create Binges that refuse to move. This takes more time in therapy to get them moving and costing more in time of money. It can also result in permanent desalidity.

I hope to continue to have the freedom to make decisions for my patients that are in their bed interest for rehabilitation. Please ansider the best ordans for the potients. This means the person who places the off the sulf orthotic device on that gersons injured hand can vest judge based on their ability to assess the needs of the patient & their injury. Berhaps most importantly the environment the detrotic force derice will be used in based on a thorough, history, evaluation and patient therapid relationsly Thelp been that relationship at its highest propessor I level becorreider this proposal sincerely hadal, ms, or 16,047

(222)

Clarkesville Drug, Inc. P.O. Box 1659 596 West Louise Street Suite D Clarkesville, Ga 30523 (706) 754-3763

May 26, 2006

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

The opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS is greatly appreciated. The following comments are those of Clarkesville Drug, Inc. and its representatives.

On the issue of competitive bidding areas, I greatly disagree with the CMS proposal that would require beneficiaries to get replacement supplies of certain items from designated providers. This would limit beneficiaries ability to get needed supplies and greatly affect my patient's healthcare.

The criteria for item solutions should never include common DMEPOS supplies like diabetes testing products. The bidding process should only apply to unique products that could be provided by a control supplier.

I strongly urge CMS to include and ensure that there is a process to include smaller supplies like my pharmacy. Please allow us to be a smaller supplier to provide for DMEPOS. We cannot compete in a large metropolitan area. If we are willing to accept the payment amount allowed, we should be allowed to be in the competitive billing program.

Please take steps to continue to allow beneficiaries access to our pharmacy and continue our provider to patient relationships. I currently provide the following types of DMEPOS in my practice, Diabetic Testing Supplies, Pulmonary Products, Influenza Vaccine, Pneumovax Vaccine.

In concluding, I hope CMS will look at the total picture and make the best decisions for the patient's welfare and care. We enjoy our jobs and take our patients healthcare very seriously. Please do not allow us to be left out.

Sincerely,

David Ledbetter, Rph Clarkesville Drug, Inc.